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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**

8 **IN RE:**

MD No. 2641

9 **BARD IVC FILTERS**
10 **PRODUCTS LIABILITY LITIGATION**

STIPULATED PROTECTIVE
ORDER

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13 The parties, through their respective counsel, stipulate to the entry of a protective
14 order to govern the dissemination of documents, materials, and other information,
15 including the substance and content thereof, designated by any party as confidential and
16 produced by any party in support of motions, in response to written discovery, or during
17 any formal or informal discovery in this litigation subject to the terms as set forth below.

18 WHEREAS, the defendants to this action, through their counsel, have requested of
19 the plaintiffs that a protective order preserving the confidentiality of certain documents
20 and information should be entered by the Court.

21 THEREFORE, IT IS ORDERED as follows:

22 **I. Definitions**

23 1. **Confidential Information.** “Confidential Information” is defined herein as
24 any information that constitutes, reflects, discloses, or contains: (1) a “trade secret” or
25 other confidential research, development, or commercial information” that is suitable for
26 protection under Federal Rule of Civil Procedure 26(c)(1)(G); and (2) information that
27 may be protected from disclosure under a party’s constitutional right of privacy such as
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1 confidential and private psychiatric, psychological, medical condition and/or employment
2 information.

3 2. **Trade Secret.** A party, in designating information “Confidential” because
4 it contains a “Trade Secret”, shall designate only information that meets the definition of
5 trade secret contained in 18 U.S.C.A. §1839 (West):

6 the term “trade secret” means all forms and types of financial, business,
7 scientific, technical, economic, or engineering information, including
8 patterns, plans, compilations, program devices, formulas, designs,
9 prototypes, methods, techniques, processes, procedures, programs, or
codes, whether tangible or intangible, and whether or how stored,
compiled, or memorialized physically, electronically, graphically,
photographically, or in writing if --

10 (A) the owner thereof has taken reasonable measures to keep such
11 information secret; and

12 (B) the information derives independent economic value, actual or
13 potential, from not being generally known to, and not being readily
ascertainable through proper means by, the public.

14 3. **This Action.** “This Action” means IN RE: BARD IVC FILTERS
15 PRODUCTS LIABILITY LITIGATION, MDL No. 2641, pending in the transferee
16 district, the United States District Court District of Arizona, as per the Transfer Order
17 issued by the United States Judicial Panel on Multidistrict Litigation on August 17, 2015
18 (Doc. 31) and all cases filed in or transferred to the District of Arizona as a result of the
19 Transfer Order in the above captioned matter.

20 **II. Information Within the Scope of the Protective Order**

21 4. This Protective Order shall govern all hard copy and electronic materials,
22 the information contained therein, and all other information produced or disclosed during
23 This Action, including all copies, excerpts summaries, or compilations thereof, whether
24 revealed in a document, deposition, other testimony, discovery response or otherwise, by
25 any party to This Action or its representatives (the “Supplying Party”) to any other party
26 or parties to This Action or their representatives (the “Receiving Party”), whether
27 provided voluntarily, pursuant to formal discovery procedures, or otherwise.
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1 5. The scope of confidentiality protections afforded under this Protective Order
2 does not include any trial exhibits or trial testimony entered into evidence during the case
3 known as *Phillips v. C.R. Bard, Inc., et al.*, No. 3:12-cv-00344-RCJ-WGC (D. Nev. June
4 1, 2015) (*See, Exhibit C*, Order denying Bard’s motion to seal trial exhibits and trial
5 transcripts, Doc. No. 328). Notwithstanding the foregoing, this Protective Order does not
6 address or alter whether or not Defendants may argue that non-confidential documents
7 should still be entitled to protection under the work-product doctrine and/or the attorney-
8 client communication privilege.

9 **III. Designating Information As “Confidential” Pursuant to This Protective Order**

10 6. **Documents.** Any Supplying Party producing documents that contain
11 information that meets the definition of Confidential Information as provided in
12 Paragraph 1 and 2 herein, may designate the contents of the documents as “Confidential”
13 prior to or at the time of production by placing the following designation on the
14 documents: “CONFIDENTIAL – Subject to Protective Order”. Where a document
15 consists of more than one page, each page of the document shall be designated as such.
16 Any document or information for which it is impracticable or impossible to affix such a
17 legend may be designated by written notice to that effect with a reasonable description of
18 the material in question including a BATES number, where applicable.

19 7. If a Supplying Party makes documents or information available for
20 inspection, rather than delivering copies to another party, no “Confidential” designation is
21 required in advance of the initial inspection. For the purposes of initial inspection only,
22 the documents shall be considered “CONFIDENTIAL”. Upon production of the
23 inspected documents, the Supplying Party shall designate which of the produced or copied
24 documents and materials are or contain Confidential Information pursuant to Paragraph 6
25 of this Order.

26 8. **Written Discovery.** If responses to written discovery contain Confidential
27 Information as defined in Paragraph 1 and 2 of this Protective Order, the Responding
28 Party may designate the responsive documents and information, as set forth in

1 Paragraph 6, with specific indication of the page and line references of the material that is
2 “Confidential” under the terms of this Protective Order.

3 9. **Depositions.** The parties may designate as Confidential any deposition
4 transcript, or portions thereof, in This Action that meets the definition of Confidential
5 Information provided in Paragraphs 1 and 2 of this Protective Order. Counsel for the
6 designating party shall advise the court reporter and the parties on the record during the
7 deposition or by letter no later than thirty (30) calendar days after the court reporter
8 provides the parties with the final deposition transcript. If any portion or all of a
9 deposition transcript is designated as Confidential Information, the court reporter shall
10 label the cover page of the original and one copy of the transcript to state that Confidential
11 Information is contained therein, and shall label as “Confidential” each page of the
12 transcript and/or exhibits to the deposition transcript that constitute “Confidential
13 Information”. Confidential designations of transcripts or portions thereof, apply to audio,
14 video, or other recordings of the testimony. The court reporter shall clearly mark any
15 transcript or portion thereof prior to the expiration of the 30-day period as “DO NOT
16 DISCLOSE – SUBJECT TO FURTHER CONFIDENTIALITY REVIEW.” Deposition
17 transcripts or portions thereof will be treated as Confidential Information until expiration
18 of the 30-day period. If any party does not designate the transcript as “Confidential”
19 either at the time of the deposition or within the 30-day period defined above, no portion
20 of the entire transcript will be deemed “Confidential” and the “DO NOT DISCLOSE-
21 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW” legend shall be removed.
22 The 30-day period may not be extended without mutual agreement of the parties.

23 10. **Confidential Information Produced By Third Parties.** A party in This
24 Action may designate as Confidential any document, information, or testimony produced
25 or supplied by any person or entity not a party to This Action, that constitutes or meets the
26 definition of Confidential Information as defined in Paragraphs 1 and 2 of this Protective
27 Order. The party claiming confidentiality shall designate the information as such within
28 thirty (30) days of its receipt of such information. Any party receiving information from a

1 third party shall treat such information as Confidential Information during this thirty (30)
2 day period while all parties have an opportunity to review the information and to
3 determine whether it should be designated as confidential. Any party designating third
4 party information as Confidential Information shall have the same rights, duties, and
5 obligations, as a Supplying Party under this Protective Order.

6 11. **Publicly Available Information.** The confidentiality restrictions and
7 confidentiality obligations set forth herein shall not apply to information that is at the time
8 of production or disclosure, or subsequently becomes, through no wrongful act on the part
9 of the Receiving Party, generally available to the public through publication or otherwise.
10 This includes information published during public hearings and trials, if the Supplying
11 Party does not move to seal or appeal any order denying such motion to seal within the
12 time permitted under the applicable rules. Notwithstanding the foregoing, this Protective
13 Order does not address or alter whether or not Defendants may argue that non-confidential
14 documents should still be entitled to protection under the work-product doctrine and/or the
15 attorney-client communication privilege.

16 **IV. Limitations on Use of Confidential Information**

17 12. All Confidential Information shall be used for the purpose of this lawsuit
18 only, and except as permitted by this Order, the parties and their respective attorneys, as
19 well as experts or consultants, shall not give, show, or otherwise divulge or disclose the
20 Confidential Information, or any copies, prints, negatives or summaries thereof to any
21 person or entity. Notwithstanding the foregoing provisions of this paragraph, nothing in
22 this Order shall prevent the use of any of the documents or electronically stored
23 information (“ESI”) produced pursuant to this Protective Order in other actions brought
24 by the plaintiff’s counsel, so long as a comparable protective order is entered in those
25 other actions.

26 13. Confidential Information pursuant to this Protective Order shall be treated
27 by the parties, their counsel, and any other signatory to this Protective Order as being
28 confidential and private. Any copy of Confidential Information shall have the same status

1 as the original. The disclosure and use of Confidential Information shall be confined to
2 the permissible disclosures and uses set forth in this Protective Order, and no one shall
3 disclose or use Confidential Information in a manner inconsistent with the terms and the
4 intent of this Protective Order.

5 14. Confidential Information may be disclosed only to the following persons
6 and shall be used solely for the litigation of This Action and may not be disclosed to
7 anyone not authorized under this paragraph:

- 8 a. Parties, their representatives, in-house counsel and regular employees
9 who are actively engaged in, or actively overseeing This Action;
- 10 b. Counsel of record, their associated attorneys, and support staff,
11 including paralegal and secretarial personnel who are working on
12 This Action;
- 13 c. Experts and consultants (including their employees/contractors) who
14 are consulted or retained by a party to assist in the litigation of This
15 Action;
- 16 d. Third-party contractors and their employees who are consulted or
17 retained by one or more parties to provide litigation-support or copy
18 services in connection with the litigation of This Action
- 19 e. Witnesses or prospective witnesses in This Action;
- 20 f. Court reporters, videographers, and other persons involved in
21 recording deposition testimony in This Action;
- 22 g. The Court and its personnel, including any mediators and/or special
23 masters appointed by the Court, or if an appeal, the court with
24 appellate jurisdiction; and
- 25 h. Jurors in This Action

26 15. Prior to the disclosure of any Confidential Information to any person
27 identified in Paragraph 14 above (except the Court and its personnel and jurors in This
28 Action), the disclosing party will provide each potential recipient of Confidential

1 Information with a copy of this Protective Order, which said recipient shall read. Upon
2 reading this Protective Order, such person shall sign an Acknowledgment, annexed to this
3 Protective Order as **Exhibit A**, acknowledging that he or she has read this Protective
4 Order and shall abide by its terms. Notwithstanding the foregoing provision, Confidential
5 Information may be disclosed to a witness who will not sign an Acknowledgment in a
6 deposition at which the party who has designated the Confidential Information is
7 represented or has been given notice that Confidential Information produced by the party
8 may be used. These Acknowledgments are strictly confidential and shall be maintained
9 by counsel for each party and only with good cause shown and separate court order will
10 the Acknowledgments be disclosed to the opposing side. Persons who come into contact
11 with Confidential Information for clerical or administrative purposes, and who do not
12 retain copies or extracts thereof, are not required to execute Acknowledgments but must
13 comply with the terms of this Protective Order.

14 16. All persons receiving or given access to Confidential Information in
15 accordance with the terms of this Order consent to the continuing jurisdiction of this Court
16 for the purposes of enforcing this Order and remedying any violations thereof.

17 17. Confidential Information shall not be placed or deposited in any sort of data
18 bank that is made available for indiscriminate or general circulation to lawyers, litigants,
19 consultants, expert witnesses or any other persons not working on This Action and not
20 signatories to this Protective Order. This paragraph and the other provisions of this Order
21 shall not apply to materials which, if challenged by any party, the Court rules are not
22 entitled to protection. This paragraph does not limit or restrict in any way the manner in
23 which a party may store and make Confidential Information available to the attorneys,
24 support staff, experts, and any other persons or entities working on This Action, provided
25 the general terms of this Order are followed.

26 18. The parties and their counsel as well as their technical consultants and
27 experts shall also not sell, offer, advertise, publicize nor provide under any condition any
28 Confidential Information produced by any other party to any competitor of any defendant

1 or to any employee or any competitor (irrespective of whether they are retained as an
2 expert by a party in This Action).

3 19. In the event that either of the parties is served by a non-party with a
4 subpoena for Confidential Information that was originally provided and claimed as
5 Confidential by another party, the Receiving Party will give notice to the Supplying Party,
6 where reasonably possible, no less than ten (10) business days prior to disclosure by
7 providing a copy of the subpoena, to allow a reasonable opportunity for the Supplying
8 Party to object to such production before any production takes place.

9 20. If a Receiving Party learns of any unauthorized disclosure of Confidential
10 Information, it shall take reasonable efforts to immediately (a) inform the Supplying Party
11 in writing of such disclosure, including to whom the material was disclosed; (b) make a
12 reasonable effort to retrieve all copies of the Confidential Information only to the extent
13 the Receiving Party has control over the unauthorized disclosed documents; (c) and to the
14 extent the Receiving party has control over the person or persons to whom unauthorized
15 disclosures were made, inform the persons of the terms of this Protective Order.

16 **V. Changes In and Objections to Designation of Information**

17 21. **Inadvertent Disclosure of Confidential Information.** If a Supplying Party
18 through inadvertence produces any documents containing Confidential Information
19 without designating the documents as such in accordance with Paragraph 6 of this
20 Protective Order, such inadvertence does not waive any claim for confidentiality that the
21 Supplying Party may possess so long as the Supplying Party notifies the Receiving Party
22 of the Confidential Information designation in writing within twenty (20) days of the date
23 that the Supplying Party became aware or reasonably should have become aware of the
24 failure to designate the information as Confidential Information. If a Supplying Party fails
25 to designate information as Confidential Information within this twenty (20) day period,
26 the Supplying Party waives its right to designate the documents as Confidential
27 Information. The Supplying Party shall also supply the Receiving Party with a new copy
28 of the documents designated in accordance with Paragraph 6 of this Protective Order,

1 which shall be substituted for the undesignated documents. Upon receipt of the substitute
2 documents, the Supplying Party shall promptly return or destroy the improperly-
3 designated document(s). Upon receipt of the Supplying Party's notice of the inadvertent
4 disclosure, the Receiving Party shall, within a reasonable time, not exceed twenty (20)
5 days, (a) treat such material in accordance with this Order; (b) take reasonable steps to
6 notify any person to whom the Receiving Party disclosed such information of the new
7 confidential designation; (c) take reasonable steps to procure the return of all copies of
8 such material from any such persons who are not entitled to receipt of Confidential
9 Information under the terms of this Protective Order ; (d) request in writing that such
10 person procure the return of such information from any person to whom such person may
11 have disclosed the information.

12 Notwithstanding the foregoing provisions of this section, the Supplying Party shall
13 be deemed to have waived any claim of confidentiality with respect to the information
14 inadvertently not claimed as confidential to which the Supplying Party fails to claim as
15 Confidential Information, prior to sixty (60) days from the close of discovery.

16 **22. Challenges to Designation of Confidential Information.** A Receiving
17 Party may challenge a Supplying Party's designation or redesignation by notifying the
18 Supplying Party in writing that the confidentiality designation does not meet the definition
19 of "Confidential Information". The designation by any party of Confidential Information
20 raises no presumption that the information or documents are entitled under the law to
21 protection. If any party contends, in writing, that any document, material, ESI, or other
22 thing has been erroneously designated as Confidential Information, the party who
23 designated the information as Confidential Information shall initiate a meet and confer
24 within ten (10) days with the opposing party and the parties shall make a good faith effort
25 to resolve issues relating to such designations. After the meet and confer, the party who
26 designated the information as Confidential Information shall file a motion with the Court
27 within thirty (30) days of receiving such written notification establishing that the
28 information is entitled to protection as Confidential Information under the law. If the

1 designating party fails to timely file such a motion within the allotted thirty (30) day
2 period, the document, ESI, material, or other thing, which is designated as Confidential
3 Information, shall forthwith be produced and be deemed not to be Confidential
4 Information. Any information or thing being challenged as inappropriately designated as
5 Confidential Information shall nonetheless be treated as Confidential Information unless
6 and until either (a) the designating party gives written permission to do otherwise, (b) the
7 designating party fails to file a motion establishing that the challenged material is subject
8 to protection as Confidential Information under the law within the thirty (30) day time
9 period, or (c) the Court rules that the document, material, ESI, or other thing shall not be
10 treated as confidential. Should the Court rule that any item designated as Confidential
11 Information is not entitled to protection under the law, the designating party shall, within
12 fourteen (14) days after all appeals are exhausted, provide the party challenging the
13 confidential designation with copies of each item free of any language indicating that the
14 item is subject to a Protective Order.

15 23. **Nothing in this Order shall be deemed to shift the burden of proof to**
16 **the party challenging the confidential designation with regard to whether the**
17 **materials produced pursuant to his Order are entitled to protection under the law as**
18 **Confidential Information.**

19 **VI. Filing Under Seal**

20 24. **Where a Party Files Documents and Contends the Documents Should**
21 **be Kept Sealed.** Where a party intends to file documents that contain Confidential
22 Information with the Court, said party must file a motion for an order sealing the
23 documents consistent with applicable law and comply with the provisions of Local Rule
24 of Civil Procedure 5.6. A copy of the motion must be served on all parties that have
25 appeared in the case.

26 25. **Where a Party Files Documents Claimed as Confidential by Another**
27 **Party.** A party that files or intends to file with the Court Confidential Information
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1 produced by another party but does not intend to request to have the records sealed, must
2 do the following:

- 3 a. Make arrangements consistent with Local Rule of Civil Procedure
4 5.6 to lodge the documents under seal in accordance with local rules.
- 5 b. File redacted copies of the documents (if appropriate) so that they do
6 not disclose the contents of the records that are subject to the
7 confidentiality agreement or protective order;
- 8 c. Serve a copy of the motion on all parties that have appeared in the
9 case; and
- 10 d. Give written notice to the party that produced the documents that the
11 documents will be placed in the public court file unless the party files
12 a timely motion to seal records.

13 If the party that produced the Confidential Information and was served with the above-
14 mentioned notice fails to file a motion to seal the records within fifteen (15) days of
15 receipt of the notice referenced in subsection 25(d) or to obtain a court order extending the
16 time to file such motion, the clerk must promptly remove all the documents filed under
17 seal pursuant to this provision from the envelope or container where they are located and
18 place them in the public file. If the party files a motion or an application to seal within
19 fifteen (15) days of receipt of the notice referenced in subsection 25(d) days or such later
20 time as the Court has ordered, these documents are to remain conditionally under seal
21 until the Court rules on the motion or application and thereafter are to be filed as ordered
22 by the Court.

23 This section shall not apply with respect to documents admitted into evidence as
24 exhibits at the trial of this matter. The Supplying Party reserves the right, however, to
25 petition the Court for protection with respect to such documents admitted into evidence as
26 exhibits at trial.

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1 **VII. Miscellaneous Provisions**

2 26. **Amending or Modifying Protective Order.** By written agreement of the
3 parties, or upon motion and order of the Court, the terms of this Protective Order may be
4 amended or modified. This Protective Order shall continue in force until amended or
5 modified by consent or agreement of the parties or by order of the Court, and shall survive
6 any final judgment or settlement in This Action, including but not limited to any final
7 adjudication of any appeals petitions for extraordinary writs, unless otherwise vacated or
8 modified by the Court. The Court shall have continuing jurisdiction over the terms and
9 provisions of this Protective Order.

10 27. **After Final Adjudication.** Upon written demand by the Supplying Party
11 made within thirty (30) days after final adjudication of This Action, including but not
12 limited to, any final adjudication of any appeals and petitions for extraordinary writs, the
13 Receiving Party shall assemble and return all Confidential Information to the Supplying
14 Party or, alternatively, shall destroy all such material at the Supplying Party's expense.
15 The Receiving Party shall verify the complete destruction or return to the Supplying Party
16 all such Confidential Information by executing and mailing to counsel for the Supplying
17 Party an Acknowledgment in the form attached hereto as **Exhibit B**. A copy of each such
18 executed Acknowledgment shall be maintained by counsel for the Receiving Party and
19 counsel for the Supplying Party. Notwithstanding the foregoing provisions of this
20 paragraph, the Receiving Party may maintain its privileged communications, work
21 product, Acknowledgments pursuant to the Protective Order, materials required to be
22 retained pursuant to applicable law, and all court-filed documents even though they
23 contain Confidential Information, but such materials shall remain subject to the terms of
24 this Protective Order. This provision may not be invoked while the plaintiff's attorneys of
25 record have active pending cases relating to IVC Filters manufactured by C.R. Bard, Inc.
26 and/or Bard Peripheral Vascular, Inc.

27 28. The terms of this Protective Order do not preclude, limit, restrict, or
28 otherwise apply to the use of Confidential Information at trial. The use of Confidential

1 Information during trial will be addressed in a later agreement between the parties, or, if
2 they cannot reach an agreement, by further order of the Court.

3 29. Nothing in this Order shall be deemed a waiver of any parties' right to
4 oppose any motion by any other party for a protective order or to oppose any objection to
5 the disclosure of any information or documents on any legal grounds, including, but not
6 limited to, the grounds that the party seeking the protective order has neither timely nor
7 adequately objected to disclosure of such documents and information or moved for a
8 protective order.

9 30. This Protective Order does not relieve any party of its obligations to respond
10 to otherwise proper discovery in This Action. Nothing contained in this Order, or any
11 action taken pursuant to it shall waive or impair any party's right to assert claims of
12 privilege or work product protection, or the right of any party to object to the relevancy of
13 admissibility of documents or information sought or produced into assert objections to
14 requested discovery on grounds other than Confidential Information. This Protective
15 Order also shall not affect or create any presumption with respect to the right of any party
16 from seeking or obtaining additional protection with respect to any documents, materials,
17 or information where allowed by law.

18 31. **Inadvertent Production.** Pursuant to Rule 502 of the Federal Rules of
19 Evidence, inadvertent production of documents or electronically-stored information
20 (hereinafter collectively "Inadvertently-Produced Documents") subject to work product
21 immunity, the attorney-client privilege, or other legal privilege protecting information
22 from discovery shall not constitute a waiver of immunity or privilege in the pending case
23 or in any other federal or state proceeding. In the event that a party inadvertently produces
24 documents or ESI subject to a claim of privilege, the Supplying Party shall, within 15
25 days of the discovery of the inadvertent disclosure, notify the other party in writing of the
26 inadvertent disclosure. The Supplying Party may, in the notice, request a "clawback" of
27 the inadvertently disclosed material. Upon receiving notice of the inadvertent production,
28 the parties agree to follow the procedures provided by Federal Rules of Civil

1 Procedure 26 (b)(5)(B) respect to the clawback of the Inadvertently Produced Documents.
2 All notes or other work product of the Receiving Party, reflecting the contents of such
3 materials, shall be destroyed and not used.

4 If the party receiving such Inadvertently-Produced Documents moves the Court to
5 dispute the claim of privilege or immunity, the party shall not assert the fact or
6 circumstances of the inadvertent production to challenge whether the material is, in fact,
7 privileged. Likewise, as part of any such motion, the Receiving Party shall not challenge
8 the “reasonable steps”, as described in Rule 502(b) of the Federal Rules of Evidence,
9 taken or not taken by the Supplying Party.

10 Pursuant to Rule 502(d) of the Federal Rules of Evidence, there is no waiver of
11 privilege or work product immunity in this matter or any other matter in any other
12 jurisdiction for any document or ESI returned or destroyed under this subsection, or for
13 the subject matter of any such document or ESI, whether the privileged document or ESI
14 was inadvertently produced following review or as part of a “Quick Peek” production. In
15 the event that either party receives information produced in discovery from the other party
16 that reasonably appears to be Inadvertently-Produced Documents, the Receiving Party
17 shall promptly notify the Supplying Party in writing of the apparent inadvertent
18 production.


19 32. Each party shall retain all rights and remedies available to it under the law
20 for the enforcement of this Protective Order against anyone who violates it.

21 33. Nothing in this Protective Order shall be construed to prevent this Court
22 from disclosing any facts the Court relies upon in making any findings or issuing any
23 ruling, order, judgment, or decree.

24 34. Within thirty (30) days of any information that has been claimed as
25 Confidential Information being de-designated or made publically available, the Supplying
26 Party shall provide notice of the Confidential Information that has been de-designated
27 and/or made publicly available. Such notice shall be made by identifying bates numbers
28 or by other means such as identifying categories of information where the identification of

1 bates numbers are not possible or not feasible. Publically available includes documents
2 that have been filed with any court or entered as an exhibit during trial not under seal,
3 provided, however that the Supplying Party is not required to provide notice of de-
4 designation with regard to such documents until any motion or request to seal those
5 documents is denied. This paragraph only applies to the extent that the Supplying Party
6 knew or should have known that the information claimed as Confidential Information was
7 de-designated or made publically available.

8 Dated this 9th day of November, 2015.

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13 David G. Campbell
14 United States District Judge
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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

**IN RE: BARD IVC FILTERS
PRODUCTS LIABILITY LITIGATION**

No. MD-15-02641-PHX-DGC

**AGREEMENT TO MAINTAIN
CONFIDENTIALITY**

I, _____ (Name), have been given and have read a copy of the Protective Order, dated _____, 2015 in the case of MDL No. 2641, pending in the United States District Court District of Arizona. I understand and will strictly adhere to the contents of said Order. I understand that produced material disclosed to me is subject to the Order of this Court and that I am prohibited from copying, disclosing or otherwise using such material except as provided by said court Order. I understand that my unauthorized disclosure of any "Confidential Information" may constitute contempt of court and I agree to be personally subject to the jurisdiction of this Court for the purpose of enforcing my obligations under this Agreement, the Order, and any contempt proceeding that may be instituted for my violation of the terms of this Acknowledgment and the Protective Order. I also understand that my signature on this "Agreement to Maintain Confidentiality", indicating my agreement to be bound by the terms of this Protective Order, is required before I may be allowed to receive and review any produced document and materials that are designated as "Confidential Information".

Date: _____

Print Signature: _____

Signature: _____

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

**IN RE: BARD IVC FILTERS
PRODUCTS LIABILITY LITIGATION**

No. MD-15-02641-PHX-DGC

**ACKNOWLEDGEMENT OF
DESTRUCTION OR RETURN OF
CONFIDENTIAL INFORMATION**

I, _____ (Name), am over the age of 18 years and am a resident of _____ County, _____. I make this Declaration based upon my personal knowledge, and I am competent to testify to the matters stated herein.

I have requested and received from _____ all of the “Confidential Information” contained in materials, transcripts, and other things within the scope of this Protective Order and produced in this case MDL No. 2641, pending in the United States District Court District of Arizona.

I have either destroyed or have attached hereto all of the “Confidential Information” contained in the materials, transcripts, and other things within the scope of this Protective Order including those materials which were returned to me by the experts and consultants mentioned above in accordance with the preceding paragraph, and as described in the Protective Order related to this matter. Notwithstanding the foregoing provisions of this paragraph, the Receiving Party may maintain its privileged communications, work product, Acknowledgments pursuant to the Protective Order, materials required to be retained pursuant to the applicable law, and all court-filed documents even though they contain “Confidential Information,” but such materials shall remain subject to the terms of this Protective Order.

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1 I declare under penalty of perjury under the laws of the United States of America
2 that the foregoing is true and correct.

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4 Date: _____

Print Signature: _____

5 Signature: _____
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EXHIBIT C

[PHILLIPS ORDER ON MOTION TO SEAL, 6.1.15]

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4 **UNITED STATES DISTRICT COURT**
5 **DISTRICT OF NEVADA**
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7 KEVIN PHILLIPS,

8 Plaintiff,

9 vs.

10 C.R. BARD, INC. et al.,

11 Defendants.
12

3:12-cv-00344-RCJ-WGC

ORDER

13 This case arises out of an allegedly defective medical device. The parties settled during
14 trial. Defendants have asked the Court to seal certain trial exhibits and portions of the trial
15 transcript.

16 A court may “make any order which justice requires to protect the party or person from
17 annoyance, embarrassment, oppression or undue burden or expense” upon motion by a party or a
18 person from whom discovery is sought. Fed. R. Civ. Pro. 26(c). “The mere fact that the
19 production of records may lead to a litigant’s embarrassment, incrimination, or exposure to
20 further litigation will not, without more, compel the court to seal its records. *Kamakana v. City &*
21 *Cnty. of Honolulu*, 447 F.3d 1172, 1179 (9th Cir.2006). There is a strong presumption towards
22 public access to judicial records. *See id.* at 1178. Under *Kamakana*, judicial records are
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1 separated into two groups, each with its own standard to be met if litigants wish to seal them.
2 First, judicial records attached to dispositive motions must meet the “compelling reasons”
3 standard in order for those documents to be sealed. *Id.* at 1180. Those compelling reasons must
4 outweigh the competing interests of the public in gaining access to the judicial records and to
5 understand the judicial process. *Id.* at 1178–79. Second, judicial records attached to
6 nondispositive motions must meet the lesser “good cause” standard to be sealed. *Id.* A motion to
7 seal transcripts and evidence adduced at trial must satisfy the “compelling reasons” test, because
8 a trial is a dispositive proceeding. *In re Elec. Arts, Inc.*, 298 Fed. App’x 568, 569 (9th Cir. 2008).
9 The Court of Appeals has rejected requests to seal documents under the “compelling reasons”
10 standard where the movant makes nothing more than “conclusory statements about the content of
11 the documents—that they are confidential and that, in general,” their disclosure would harm the
12 movant. *Id.* at 1182.

13 Defendants argue that three categories of material should be sealed: (1) product design
14 and testing, including confidential communications between Defendants and the FDA; (2) sales
15 and marketing information; and (3) Defendant’s internal quality control procedures, complaint
16 and adverse event responses, reporting and handling, device tracking procedures, and corrective
17 action procedures. The Court finds that these categories of information do not satisfy the
18 compelling reasons test. The only harm that could come to Defendants from the release of this
19 information is the precipitation of further lawsuits against it. Preventing lawsuits due to the
20 release of inculpatory information is not a compelling reason to seal otherwise public legal
21 proceedings. Indeed, the exposure of facts relevant to the material claims in a lawsuit is the
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1 purpose of a trial, and these facts should remain public unless the harm likely to result from their
2 release is unrelated to the nature of the claims. The information does not directly implicate trade
3 secrets.

4 Even if the test could be satisfied, Plaintiff correctly notes that Defendants have waived
5 the issue because Defendants made no motion to seal the exhibits or testimony at the public trial.
6 *See, e.g., Gambale v. Deutsche Bank AG*, 377 F.3d 133, 144 & n.11 (2nd Cir. 2004); *Littlejohn v.*
7 *BIC Corp.*, 851 F.2d 673, 680 (3d Cir. 1988); *Nat'l Polymer Prods. v. Borg-Warner Corp.*, 641
8 F.2d 418, 421 (6th Cir. 1981); *Level 3 Commc'ns, LLC v. Limelight Networks, Inc.*, 611 F. Supp.
9 2d 572, 588 (E. D. Va. 2009) ("The First Amendment public right of access to these exhibits
10 sprang into existence upon their being offered into evidence for the jury's consideration at trial,
11 and since no request was made to seal them prior to or at that time, Savvis waived any future
12 right to assert any competing interest to be weighed by the Court and, thus, any objection to the
13 public availability of the exhibits in the Court's files.").

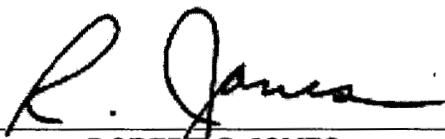
14 CONCLUSION

15 IT IS HEREBY ORDERED that the Motion to Seal (ECF No. 317) is DENIED.

16 IT IS FURTHER ORDERED that the Motion (ECF No. 326) is DENIED without
17 prejudice, as it has been incompletely filed.

18 IT IS SO ORDERED.

19 Dated this 1st day of June, 2015.

20 
21 ROBERT C. JONES
22 United States District Judge
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1 **WO**

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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**

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9 IN RE: Bard IVC Filters Products Liability
10 Litigation,
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No. MDL 15-02641-PHX DGC
ORDER

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14 This multidistrict litigation (“MDL”) involves more than 3,000 personal injury
15 cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.
16 (collectively, “Bard”). Bard manufactures and markets medical devices, including
17 inferior vena cava (“IVC”) filters. Each Plaintiff received a Bard IVC filter implant and
18 claims that the filter is defective and has caused Plaintiff to suffer serious injury or death.
19 Plaintiffs assert various state law claims and seek both compensatory and punitive
20 damages.

21 In this motion, Bard seeks summary judgment on the ground that Plaintiffs’ state
22 claims are expressly preempted by the Medical Device Amendments of 1976 (“MDA”),
23 21 U.S.C. § 360 et seq., and impliedly preempted by the MDA under the Supreme
24 Court’s conflict preemption principles. Doc. 5396. The motion is fully briefed, and the
25 Court heard oral arguments on November 17, 2017. The Court will deny Bard’s motion.

26 **I. Background.**

27 The Court will begin by describing IVC filters and their uses, the history of the
28 MDA, the relevant regulatory process, and the claims asserted by Plaintiffs.

1 **A. IVC Filters.**

2 The IVC is a large vein that carries de-oxygenated blood from the lower body to
3 the heart. IVC filters are small metal devices implanted in the upper portion of the IVC
4 to stop blood clots from travelling to the heart and lungs. Blood clots often develop in
5 the legs from a condition called deep vein thrombosis or “DVT.” Once blood clots reach
6 the lungs, they are deemed pulmonary emboli or “PE.” Pulmonary emboli and other
7 thromboembolic events, such as strokes, can cause serious injury or death.

8 People at risk for DVT and PE may be prescribed blood thinners such as Heparin
9 or Warfarin to help prevent blood clots. But these medications do not prevent blood
10 clotting for certain people at high risk for DVT or PE, and blood thinners may not be an
11 option for bariatric and trauma patients who could experience thromboembolic events
12 during surgery. In those situations, physicians may recommend implanting an IVC filter
13 to catch any blood clots before they reach a vital organ.

14 IVC filters originally were designed to be implanted permanently. Because some
15 patients need only temporary filters, however, medical device manufacturers such as
16 Bard developed retrievable filters. Bard first obtained Food and Drug Administration
17 (“FDA”) clearance to market a retrievable IVC filter in 2003. Seven different versions of
18 Bard filters are at issue in this MDL – the Recovery, G2, G2 Express, G2X, Eclipse,
19 Meridian, and Denali. They are spider-shaped devices with multiple struts fanning out
20 from a cone-shaped head. The struts consist of legs with hooks that attach to the IVC
21 wall, and shorter curved arms that serve to catch or break up blood clots. Each of these
22 filters is a variation of its predecessor. The last-generation Denali filter received FDA
23 clearance in May 2013. The filters are designed to be retrievable using Bard’s Recovery
24 Cone Removal System.

25 **B. History of the MDA.**

26 Throughout our history, states have exercised police powers to protect the health
27 and safety of their residents. The federal government first entered this field more than a
28 century ago with passage of the Food and Drug Act of 1906, 34 Stat. 768, which

1 prohibited the manufacture of adulterated or misbranded food and drugs. Congress
2 broadened the coverage of the statute to include misbranded or adulterated cosmetics
3 and medical devices in the Food, Drug, and Cosmetic Act of 1938 (“FDCA”), 52 Stat.
4 1040, as amended, 21 U.S.C. § 301 et seq.

5 The FDCA required premarket approval for new drugs, but not new medical
6 devices. As technology advanced and reliance on medical devices grew, policymakers
7 and the public became concerned about the increasing number of injuries resulting from
8 device failures. Notable in this regard were injuries women suffered from the Dalkon
9 Shield contraceptive device in the 1960s and early 1970s. Other devices, including
10 catheters, artificial heart valves, and pacemakers, also created possible health risks.
11 Several states responded with regulatory measures, such as California’s 1970 law
12 requiring premarket approval of medical devices. 1970 Cal. Stats. ch. 1573, §§ 26670-
13 26693.

14 In 1976, Congress passed the MDA “to provide for the safety and effectiveness of
15 medical device[s] intended for human use[.]” Pub. L. No. 94-295, 90 Stat. 539 (1976).
16 The MDA extends coverage of the FDCA to medical devices through federal oversight
17 measures implemented by the FDA. It also curtails state regulation of medical devices
18 through a provision that preempts state requirements that differ from or add to federal
19 requirements. 21 U.S.C. § 360k.

20 **C. FDA Regulatory Process.**

21 The MDA gives the FDA broad powers to classify and regulate medical devices.
22 The FDA assigns medical devices to Class I, Class II, or Class III based on their risk
23 levels. Class I devices, which include products such as bandages and tongue depressors,
24 are low-risk and subject to oversight only through “general controls” such as labeling
25 requirements. 21 U.S.C. § 360c(a)(1)(A). Class II devices pose moderate health risks.
26 The original MDA definition of a Class II device identified performance standards as the
27 means by which the FDA could reasonably ensure safety and effectiveness. The Safe
28 Medical Devices Act of 1990 (“SMDA”), Pub. L. 101-629, added various “special

1 controls” for this purpose. The special controls may include FDA guidance documents,
2 premarket data requirements, performance standards, postmarket surveillance measures,
3 and patient registries. 21 U.S.C. § 360c(a)(1)(B). Class III includes devices used to
4 support human life, such as pacemakers and hearts valves, and devices that pose a high
5 risk of injury. 21 U.S.C. § 360c(a)(1)(C). They receive the highest level of regulatory
6 control.¹ IVC filters originally were designated as Class III devices, but were moved to
7 Class II, along with many other pre-MDA devices, in 2000. *See* 65 Fed. Reg. 17138,
8 17144 (Mar. 31, 2000); 21 C.F.R. § 870.3375.

9 The FDA applies different levels of scrutiny to medical devices before approving
10 or clearing them for market, and the level of scrutiny can affect whether state laws are
11 preempted. The most rigorous level of scrutiny is known as “premarket approval,” often
12 referred to as the “PMA process.” 21 U.S.C. § 360e(a). To comply, a manufacturer must
13 file an application that provides a wide range of detailed information to the FDA in order
14 to demonstrate that the device is safe and effective. *See* 21 U.S.C. § 360e(c). If the FDA
15 finds the device safe and effective, it approves the device for marketing.²

16 Others medical devices can be cleared for market through a less rigorous process
17 known as section “510(k)” review after the original statutory provision describing the
18 review. A manufacture can satisfy this level of review, and be exempt from the PMA
19 process, by providing premarket notice to the FDA that its device is “substantially
20 equivalent” to a predicate device already on the market.³ § 360c(f)(1)(A). This 510(k)

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22 ¹ *See generally FDA Medical Devices, Regulatory Controls* (last updated June 26,
2014), *available at* <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm> (last visited Nov. 17, 2017).

23
24 ² *See generally FDA Medical Devices, Device Advice: Comprehensive Regulatory Assistance* (last updated Sept. 29, 2017), *available at* <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/> (last visited Nov. 17, 2017).

25
26 ³ A “predicate device” is one that (1) was legally marketed before passage of the
MDA and no PMA process was required, (2) has been reclassified from Class III to Class
27 II or I, or (3) has been found to be a substantially equivalent device through 510(k)
review. 21 C.F.R. § 807.92(a)(3). A device is “substantially equivalent” to a predicate
28 device where it has the same intended use and (1) has “the same technological
characteristics as the predicate device,” or (2) any technological differences “do not
raise different questions of safety and effectiveness than the predicate device.”

1 review is more streamlined than the PMA process and focuses primarily on equivalence
2 rather than safety and effectiveness. If a 510(k) notice results in an FDA finding of
3 substantial equivalence, the device is cleared for marketing.

4 The FDA maintains a bright line between devices “approved” through the PMA
5 process and devices “cleared” through 510(k) review. PMA approval results in a finding
6 of safety and effectiveness, while 510(k) clearance results only in a finding of substantial
7 equivalence. FDA regulations require manufacturers to maintain this distinction:

8 Submission of a [510(k) notice] in accordance with this subpart, and a
9 subsequent determination by the Commissioner that the device intended for
10 introduction into commercial distribution . . . does not in any way denote official
11 approval of the device. Any representation that creates an impression of
12 official approval of a device because of complying with [510(k)
13 notification] is misleading and constitutes misbranding.

14 21 C.F.R § 807.97.

15 The Bard IVC filters at issue in this case, like most medical devices on the market
16 today, received FDA clearance through 510(k) review. Each Bard filter was deemed to
17 be substantially equivalent to a predicate filter already on the market. No Bard filter has
18 received FDA approval through the PMA process.

19 **D. Plaintiffs’ Claims.**

20 Plaintiffs allege that Bard IVC filters are defective. Plaintiffs contend that the
21 filters tilt, perforate the IVC, and fracture and migrate to neighboring organs such as the
22 heart and lungs. Plaintiffs claim that Bard filters are more dangerous than other kinds of
23 IVC filters, and that Bard concealed adverse information and otherwise failed to warn the
24 medical community and the public about the risks posed by its filters. Bard vigorously
25 disputes Plaintiffs’ allegations of high risk levels, contending that overall complication
26 rates associated with Bard filters are low and comparable to those of other IVC filters.

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§ 360c(i)(1)(A); *see* 21 C.F.R. § 807.100(b) (describing criteria the FDA uses in its
substantial equivalence review).

1 Plaintiffs' master complaint asserts 17 causes of action under various state laws:
2 strict product liability claims for manufacturing, information, and design defects (Counts
3 I-III); negligence claims for design, manufacturing, failure to recall or retrofit, failure to
4 warn, misrepresentation, and per se negligence (Counts IV-IX); breach of warranties
5 (Counts X-XI); fraudulent misrepresentation and concealment (Counts XII-XIII);
6 consumer fraud and unfair trade practices (Count XIV); loss of consortium (Count XV);
7 wrongful death (Count XVI); and survival claims (Count XVII). Doc. 303-1.⁴

8 Bard seeks summary judgment on each cause of action, arguing that the MDA
9 preempts them all. Doc. 5396 at 14-34.⁵ For reasons explained below, the Court finds
10 that Bard has not met its burden of establishing preemption and therefore will deny
11 summary judgment.

12 **II. Summary Judgment Standard.**

13 A party seeking summary judgment "bears the initial responsibility of informing
14 the district court of the basis for its motion, and identifying those portions of [the record]
15 which it believes demonstrate the absence of a genuine issue of material fact." *Celotex*
16 *Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the
17 moving party shows that there is no genuine dispute as to any material fact and the
18 movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Only disputes
19 over facts that might affect the outcome of the suit will preclude summary judgment, and
20 the disputed evidence must be "such that a reasonable jury could return a verdict for the
21 nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The
22 evidence of the nonmoving party is to be believed, and all reasonable inferences are to be

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24 ⁴ The master complaint is the operative pleading for most of the cases in this
25 MDL. It was created for the sake of convenience and serves as a long-form complaint
26 giving notice, pursuant to Rule 8, of the allegations that Plaintiffs assert in this case.
27 Plaintiff-specific allegations are contained in individual short-form complaints or certain
28 complaints served on Bard before the filing of the master complaint. See Doc. 249.
Plaintiffs also provide Bard with fact sheets that describe their individual conditions and
claims. See Doc. 365.

⁵ Page citations are to numbers placed at the top of each page by the Court's
electronic filing system rather than the document's original page numbers.

1 drawn in that party's favor, because the weighing of evidence and drawing of inferences
2 are jury functions. *Id.* at 255.

3 **III. Basic Preemption Principles.**

4 “When a transferee court receives a case from the MDL Panel, the transferee court
5 applies the law of the circuit in which it is located to issues of federal law.” *In re Gen.*
6 *Am. Life Ins. Co. Sales Practices Litig.*, 391 F.3d 907, 911 (8th Cir. 2004). In this case,
7 that would be the law of the Ninth Circuit. Thus, in performing its federal preemption
8 analysis, the Court will look primarily to Supreme Court and Ninth Circuit cases.

9 “The Supremacy Clause provides a clear rule that federal law ‘shall be the
10 supreme Law of the Land; and the Judges in every State shall be bound thereby, anything
11 in the Constitution or Laws of any State to the Contrary notwithstanding.’” *Arizona v.*
12 *United States*, 567 U.S. 387, 399 (2012) (quoting U.S. Const. art. VI, cl. 2). Under this
13 clause, “Congress has the power to preempt state law.” *Crosby v. Nat’l Foreign Trade*
14 *Council*, 530 U.S. 363, 372, (2000).

15 “[T]he purpose of Congress is the ultimate touchstone” in determining whether
16 Congress has preempted a state law. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516
17 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)). Federal
18 preemption may be either express or implied. *Attay v. Cty. of Maui*, 842 F.3d 688, 699
19 (9th Cir. 2016). Where there is no express congressional command, a state law is
20 impliedly preempted if “it actually conflicts with federal law[.]” *Id.* (citing *Cipollone*,
21 505 U.S. at 516). Conflict preemption occurs “where compliance with both federal and
22 state regulations is a physical impossibility[.]” *Arizona*, 567 U.S. at 399 (internal
23 citations and quotation marks omitted).

24 “Where the intent of a statutory provision that speaks expressly to the question of
25 preemption is at issue, ‘[courts] do not invoke any presumption against pre-emption but
26 instead focus on the plain wording of the clause, which necessarily contains the best
27 evidence of Congress’ pre-emptive intent.’” *Attay*, 842 F.3d at 699 (quoting *Puerto Rico*
28 *v. Franklin Cal. Tax-Free Trust*, — U.S. —, 136 S. Ct. 1938, 1946 (2016)). Where

1 there is no express preemption and a federal statute regulates in an area “traditionally
2 occupied by states, such as health, safety, and land use, a ‘presumption against
3 preemption’ adheres.” *Gobeille v. Liberty Mut. Ins. Co.*, — U.S. —, 136 S. Ct 936, 946
4 (2016) (quoting *Wyeth v. Levine*, 555 U.S. 555, 565 n.3 (2009)).

5 The Court first will discuss express preemption under § 360k of the MDA, and
6 then turn to implied preemption.

7 **IV. Express Preemption.**

8 Section 360k of the MDA includes this express preemption clause:

9 Except as provided in subsection (b) of this section, no State or political
10 subdivision of a State may establish or continue in effect with respect to a
11 device intended for human use any requirement--

12 (1) which is different from, or in addition to, any requirement applicable
under this chapter to the device, and

13 (2) which relates to the safety or effectiveness of the device or to any other
14 matter included in a requirement applicable to the device under this chapter.

15 21 U.S.C. § 360k(a). The Supreme Court has held that this clause applies when (1) the
16 federal government has established “requirements” applicable to the device in question,
17 and (2) state law claims are based on state requirements that are different from, or in
18 addition to, the federal requirements, and that relate to safety and effectiveness. *Riegel v.*
19 *Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008). Consistent with this guidance, the Court
20 first will determine whether the FDA’s 510(k) review established federal “requirements”
21 for the Bard IVC filters, and then whether Plaintiffs’ state law claims would impose
22 “requirements” different from, or in addition to, any federal requirements.

23 **A. Federal Requirements.**

24 **1. Supreme Court Precedent.**

25 The Supreme Court has interpreted § 360k in two cases, *Riegel* and *Medtronic,*
26 *Inc. v. Lohr*, 518 U.S. 470 (1996).⁶ *Lohr* involved a pacemaker that was cleared by the

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28 ⁶ The Supreme Court addressed implied preemption under the MDA in *Buckman*
Co. v. Plaintiffs’ Legal Committee, 531 U.S. 341 (2001), but declined to express a view
on whether the state claims were expressly preempted under § 360k. *Id.* at 348 n.2.

1 FDA in 1982 through 510(k) review. The plaintiff, who suffered injuries when her
2 pacemaker failed, brought state common law claims for negligence and strict liability
3 against the manufacturer, Medtronic. The majority opinion in *Lohr* held that § 360k does
4 not preempt state law claims directed at medical devices cleared through the 510(k)
5 process because the substantial equivalence review of that process places no federal
6 requirements on a device. 518 U.S. at 492-94; *see Riegel*, 552 U.S. at 322-23.

7 Central to the holding in *Lohr* was the Supreme Court’s finding that “[t]he
8 § 510(k) notification process is by no means comparable to the PMA process[.]” 518
9 U.S. at 478-79. *Lohr* noted that the PMA process is a “rigorous” examination of the
10 product in question that takes an average of 1,200 hours to complete, while “the 510(k)
11 review is completed in an average of only 20 hours.” *Id.* at 477-79. *Lohr* noted that the
12 “510(k) process is focused on *equivalence*, not safety[.]” *Id.* at 493 (emphasis in original;
13 citation and quotation marks omitted). *Lohr* concluded that the FDA’s 510(k) review
14 “did not ‘require’ Medtronics’ pacemaker to take any particular form for any particular
15 reason; the agency simply allowed the pacemaker, as a device substantially equivalent to
16 one that existed before 1976, to be marketed without running the gauntlet of the PMA
17 process.” *Id.* at 493-94.

18 *Riegel* involved a cardiovascular catheter approved by the FDA through the PMA
19 process. *Riegel* did not disagree with *Lohr*’s conclusion that 510(k) review imposes no
20 federal requirements on manufacturers, but held that the more rigorous PMA process
21 does impose such requirements. 552 U.S. at 322. *Riegel* disagreed with *Lohr*’s view of
22 state law claims and held that such claims can impose requirements within the meaning
23 of § 360k. *Id.* at 322-24. Because the common law tort claims asserted in *Riegel* would
24 impose requirements different from federal requirements established through the PMA
25 process, *Riegel* found the plaintiffs’ state law tort claims preempted by § 360k. *Id.*
26 at 323-25.

27 *Riegel* was decided nearly 20 years after passage of the SMDA and the start of
28 FDA’s use of “special controls” during 510(k) review, and yet the Supreme Court still

1 found that 510(k) review was not close to the PMA process. *Riegel* described the PMA
2 process in detail and held that it imposes federal “requirements” within the meaning of
3 § 360k. In doing so, *Riegel* distinguished 510(k) review:

4 Premarket approval, in contrast [to 510(k) clearance], imposes
5 “requirements” under the MDA as we interpreted it in *Lohr*. Unlike
6 general labeling duties, premarket approval is specific to individual
7 devices. And it is in no sense an exemption from federal safety review—
8 it *is* federal safety review. Thus, the attributes that *Lohr* found lacking in
9 510(k) review are present here.

10 552 U.S. at 322-23 (emphasis in original).

11 *Riegel* explicitly addressed, and did not disagree with, *Lohr*’s finding that 510(k)
12 review imposes no device-specific requirements on manufacturers:

13 Even though substantial-equivalence review under 510(k) is device
14 specific, *Lohr* also rejected the manufacturer’s contention that 510(k)
15 approval imposed device-specific “requirements.” We regarded the fact
16 that products entering the market through 510(k) may be marketed only so
17 long as they remain substantial equivalents of the relevant 1976 devices as
18 a qualification for an exemption rather than a requirement.

19 552 U.S. at 322.

20 The Ninth Circuit likewise has recognized significant differences between 510(k)
21 review and the PMA process. In *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013), the
22 circuit court found a state law fraud claim preempted by the MDA because the device at
23 issue, “[l]ike the device in *Riegel*, . . . was subject to device-specific requirements under
24 the PMA [process].” *Id.* at 1118. *Perez* contrasted the 510(k) review in *Lohr*, which
25 imposes no “requirements,” with the more rigorous PMA process:

26 None of the federal laws or regulations at issue [in *Lohr*] imposed device-
27 specific requirements. In contrast, the Court in *Riegel* held that § 360k
28 preempted common-law claims challenging the safety and effectiveness of
a medical device that had received premarket approval from the FDA. Unlike the federal laws and regulations at issue in *Lohr*, premarket approval imposes device-specific requirements.

1 711 F.3d at 1118; *see also Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1230 (9th Cir.
2 2013) (en banc) (noting that the Court in *Riegel* “was careful to state that . . . *Lohr*
3 remained good law”).

4 Many cases interpret *Riegel* and *Lohr* to mean that PMA approval preempts
5 different or additional requirements imposed by state tort law, while 510(k) clearance
6 does not. *See, e.g., Hovey v. Cook Inc.*, 97 F. Supp. 3d 836, 844-46 (S.D. W. Va. Apr. 1,
7 2015) (rejecting the manufacturer’s preemption argument under § 360k and finding that
8 510(k) clearance of the medical device did not preempt state law tort claims in light of
9 *Lohr* and *Riegel*); *Horrillo v. Cook Inc.*, No. 08-60931-CIV, 2014 WL 8186704, at *3
10 (S.D. Fla. June 6, 2014) (“[U]nder *Lohr* and *Riegel*, because the stent received FDA
11 approval under the § 510(k) process, Defendant is precluded, as a matter of law, from
12 arguing that Plaintiff’s claims are preempted under the express preemption provision set
13 forth in § 360k(a).”); *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 5700513,
14 at *12 (S.D. W. Va. Oct. 18, 2013) (“[T]he 510(k) process does not address product
15 safety and efficacy and therefore is not relevant to Bard’s obligations under Georgia state
16 tort law”) (citing *Lohr* and *Riegel*); *James v. Diva Int’l, Inc.*, 803 F. Supp. 2d 945, 951
17 (Mar. 18, 2011) (“The device at issue before the Court was approved by the ‘substantially
18 equivalent’ process. Defendant argues that this is of no consequence. However, it is
19 worth noting that the Supreme Court has held that this process implements only generally
20 applicable standards and does are not constitute sufficient ‘requirements’ to trigger
21 preemption under Section 360k(a).”) (citing *Lohr*, 518 U.S. at 492-93).⁷

22 Bard argues that *Lohr* is outdated and does not control this case. Bard notes that
23 *Lohr* concerned a pacemaker cleared by the FDA in 1982, and argues that the 510(k)
24 clearance process was dramatically altered when Congress passed the SMDA in 1990.
25 Doc. 5396 at 19-20. Bard emphasizes that § 12 of the SMDA authorizes the FDA to find

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27 ⁷ This Court reached a similar conclusion in another case, finding that 510(k)
28 review for a pain pump device did not preempt Arizona negligence and strict liability
claims. *Placencia v. I-Flow Corp.*, No. CV10-2520 PHX DGC, 2012 WL 5877624, at *5
(D. Ariz. Nov. 20, 2012).

1 a device “substantially equivalent” under 510(k) review if it is “as safe and effective as a
2 legally marketed device” and “does not raise different questions of safety and efficacy
3 than the predicate device.” PL 101-629 § 12. Bard argues that this consideration of
4 safety and effectiveness was not present in *Lohr*, and, when combined with FDA
5 discretion to require clinical data and testing information, can result in 510(k) clearance
6 procedures that are closer to PMA approval and have preemptive effect. Bard argues that
7 its IVC filters went through a rigorous 510(k) review focused on safety and effectiveness.

8 The Court does not agree that *Lohr* is outdated. The SMDA did introduce safety
9 and effectiveness considerations into 510(k) review, but only comparatively. Under § 12,
10 the FDA does not make a determination that the device being cleared is safe and
11 effective; it concludes that the device is substantially equivalent to the predicate device.
12 *Id.* True, the FDA may do this by finding that the device “is as safe and effective” as the
13 predicate device, but that is still a comparative exercise. The assumption is that the
14 predicate device is safe and effective enough to be on the market, and that the proposed
15 device, if sufficiently similar, must be so as well. The FDA’s 510(k) review “continues
16 to primarily focus on equivalence as opposed to safety.” *Hovey*, 97 F. Supp. 3d at 845;
17 *see Riegel*, 552 U.S. at 323.

18 A 510(k) notice must include information regarding the device, its intended use,
19 and its planned labelling and advertising; whether it is similar to or different from
20 comparable products in commercial distribution; an assurance that the information
21 submitted is truthful and accurate; and any additional information regarding the device
22 requested by the FDA that is necessary to make a finding as to whether or not the device
23 is substantially equivalent to a predicate device. 21C.F.R. § 807.87. FDA regulations
24 provide that a 510(k) notice can result in one of several possible outcomes. The FDA can
25 (1) declare the device substantially equivalent to a predicate device, (2) declare the device
26 not substantially equivalent to any predicate device, (3) request additional information,
27 (4) withhold the decision, or (5) advise the applicant that 510(k) clearance is not required.
28 21 C.F.R. § 807.100(a). Determining that the device is safe and effective is not one of

1 the available FDA options. Indeed, because the FDA makes no determination regarding
2 the device's safety and effectiveness comparable to PMA approval, FDA regulations
3 specifically prohibit a manufacturer from "misbranding" a 510(k)-cleared device by
4 claiming that it has been "approved" by the FDA. 21 C.F.R. § 807.97.

5 The PMA process, by contrast, requires a manufacturer to show that its product is
6 sufficiently safe and effective for the U.S. market. *See Buckman*, 531 U.S. at 344-45. If
7 successful, the process results in an FDA finding of safety and effectiveness. Indeed,
8 after PMA approval, the manufacturer cannot change the design, manufacturing process,
9 labeling, or any other attribute of the product that could affect its safety or effectiveness
10 without FDA permission. § 360e(d)(6)(A)(i). The manufacturer must also report to the
11 FDA any information concerning the safety of the device that it learns after receiving
12 approval. § 360i. "[P]remarket approval is focused on safety, not equivalence." *Riegel*,
13 552 U.S. at 323. It remains fundamentally different from 510(k) review.

14 The Court cannot conclude that the *Lohr* majority was ignorant of current FDA
15 practices or the 1990 changes made by the SDMA. *Lohr* was decided six years after
16 passage of the SMDA, and any changes to 510(k) review were available to the Court in
17 interpreting Congress's intent. 518 U.S. at 480 n. 4. And yet the Court still concluded
18 that "[t]here is no suggestion in either the statutory scheme or the legislative history that
19 the § 510(k) exemption process was intended to do anything other than maintain the
20 status quo with respect to the marketing of existing medical devices and their substantial
21 equivalents." *Id.* at 494. That status quo, *Lohr* noted, "included the possibility that the
22 manufacturer of the device would have to defend itself against state-law claims of
23 negligent design." *Id.*

24 In short, *Lohr* remains good law, and clearance of a product under 510(k) usually
25 does not preempt state common law claims. But this does not mean that 510(k) clearance
26 can never result in preemption. As Bard notes, the fifth and concurring justice in the
27 *Lohr* majority, Justice Breyer, acknowledged that preemption could occur if specific
28 federal requirements were imposed on a device by the FDA. *Id.* at 503-04. And the

1 Ninth Circuit has held that state law failure-to-warn claims were preempted for a 510(k)
2 device on which the FDA imposed specific product and disease warning requirements.
3 *See Papike v. Tambrands Inc.*, 107 F.3d 737, 740 (9th Cir. 1997).

4 How, then, does one identify 510(k) cases where state law claims are preempted?
5 The preemption provision itself provides some helpful guidance. Section 360(k) gives
6 preemptive power only to requirements “applicable to the device.” 21 U.S.C. § 360(k).
7 The requirements must be device-specific. In *Lohr*, the Supreme Court also looked to a
8 regulation promulgated by the FDA – 21 C.F.R. § 808.1(d) – for help on the preemptive
9 scope of § 360(k). 518 U.S. at 498-501; *see also id.* at 506-07 (Breyer, J., concurring).
10 That regulation confirms that any preemptive requirement must specifically apply to the
11 device in question:

12 State or local requirements are preempted only when the Food and Drug
13 Administration has established *specific counterpart regulations* or there are
14 other *specific requirements applicable to a particular device* under the act,
15 thereby making any existing divergent State or local requirements
16 applicable to the device different from, or in addition to, the specific Food
and Drug Administration requirements.

17 21 C.F.R. § 808.1(d) (emphasis added).

18 Thus, preemption can occur under the 510(k) process only when the FDA has
19 imposed requirements specific to the device in question. More general FDA
20 requirements – what *Riegel* calls “federal manufacturing and labeling requirements
21 applicable across the board to almost all medical devices” – do not preempt state law
22 claims. 552 U.S. at 322. The FDA requirements must do more than reflect “entirely
23 generic concerns about device regulation generally.” *Id.* (citations to *Lohr* omitted).

24 **2. Has the FDA Imposed Specific Requirements on Bard Filters?**

25 Bard argues that the FDA has imposed three categories of specific requirements on
26 its filters: (1) special controls, primarily in the form of FDA guidance documents;
27 (2) clinical studies, and testing and design information; and (3) labelling and other
28 information requirements. Doc. 5396 at 24-30. The Court will review each category.

1 **a. Special Controls (Guidance Documents).**

2 Bard relies heavily on the special controls issued by the FDA in connection with
3 510(k) review of IVC filters generally. One of the special controls is a guidance
4 document issued in November 1999 and titled “Guidance for Cardiovascular
5 Intravascular Filter 510(k) Submissions.” 21 C.F.R. § 870.3375(b)(2)(ii); *see* Doc. 5398
6 ¶ 29, Ex. F. Bard contends that this guidance document is a “specific and detailed
7 directive the FDA issued” for IVC filters. Doc. 5396 at 24. The Court does not agree.

8 The 1999 guidance document is not a “directive” as Bard claims. It contains this
9 disclaimer: “This document is intended to provide guidance. It represents the [FDA’s]
10 current thinking It does not create or confer any rights for or on any person and
11 does not operate to bind the FDA or the public.” Doc. 5398 ¶ 29, Ex. F at 1 n.1.

12 The document describes itself as a “draft,” and makes clear that it does not
13 mandate any particular course of action. IVC filter manufacturers can obtain 510(k)
14 clearance by following “either the specific recommendations of this guidance or some
15 alternate control that provides equivalent assurances of safety and effectiveness.” *Id.*
16 at 1. Thus, manufacturers can choose between following the “recommendations” in the
17 guidance document or alternative approaches.

18 Bard emphasized at oral argument that the guidance document contains a section
19 on “Filter Performance,” but this section simply includes “an outline of the general issues
20 that need to be addressed when seeking premarket clearance for a filter” under 510(k).
21 *Id.* at 3. The section leaves it to the manufacturer to determine what tests or data should
22 be submitted: “Test protocols and acceptance criteria for these tests are the responsibility
23 of the submitter. FDA recognizes that there are many different testing methods that may
24 be used to satisfy the objective.” *Id.* The document also includes a suggested general
25 format for filter labels, but no specific regulatory mandate. Manufacturers are free to
26 include other language “specific to [their] particular device design.” *Id.* at 9-10. In short,
27 the document leaves much to the discretion of filter manufacturers and provides guidance
28 instead of imposing specific requirements. *See Thompson v. DePuy Orthopaedics, Inc.,*

1 No. 1:13-CV-00602, 2015 WL 7888387, at *10 (S.D. Ohio Dec. 4, 2015) (noting that the
2 guidance document at issue was “directed mostly to what needs to be submitted to the
3 FDA to facilitate review of the 510(k) application” and contained no “language that
4 mandates anything from the manufacturers”).⁸

5 The two other documents identified by the FDA as special controls for IVC filters
6 are (1) “Use of International Standards Organization’s ISO 10993 ‘Biological Evaluation
7 of Medical Devices Part I: Evaluation and Testing,’” and (2) “510(k) Sterility Review
8 Guidance and Revision of 2/12/90 (K90-1)” 21 U.S.C. § 870.3375(b)(1), (b)(2)(i); *see*
9 Doc. 5398 ¶ 28. These documents impose only generic requirements for all implantable
10 medical devices and offer nothing specific to IVC filter design, manufacturing,
11 performance, or labeling. Doc. 7369 at 24 n.17. As *Riegel* noted, “federal manufacturing
12 and labeling requirements applicable across the board to almost all medical devices” do
13 not preempt state common law claims. 552 U.S. at 322. Bard does not contend
14 otherwise.⁹

15 **b. Clinical Studies and Testing and Design Information.**

16 Bard places much emphasis on the fact that clinical studies were required by FDA
17 for 510(k) clearance of the Recovery, G2, and Denali filters. Doc. 5396 at 26-28. But
18 the FDA regulations state that clinical studies can be requested for the purpose of
19 deciding whether a device is substantially equivalent to a predicate device:

20 FDA will determine that a device is substantially equivalent to a predicate
21 device using the following criteria: . . .

22
23 ⁸ *Whitson v. Safeskin*, 313 F. Supp. 2d 473 (M.D. Pa. 2004), is distinguishable
24 because the FDA had established clear and specific requirements for the product in a
manual titled “Regulatory Requirements for Medical Gloves.” *Id.* at 477.

25 ⁹ In its reply brief, Bard discusses internal FDA documents relating to the decision
26 to reclassify IVC filters from Class III to Class II devices. Doc. 7828 at 8-9. Bard notes
27 that the FDA had determined that special controls would provide reasonable assurance of
28 the safety and effectiveness of IVC filters. *Id.* at 9. But this is true for all Class II
devices subject to special controls, or at least those reclassified along with IVC filters in
2000. *See* 65 Fed. Reg. 17138-01 (Mar. 31, 2000). Bard cites no legal authority for the
proposition that mere reclassification, or assignment of special controls to a device
cleared through 510(k) review, imposes “requirements” for purposes of § 360k.

1
2 (B) The data submitted establishes that the device is substantially
3 equivalent to the predicate device and contains information, *including*
4 *clinical data if deemed necessary by the Commissioner*, that demonstrates
5 that the device is as safe and as effective as a legally marketed device[.]

6 21 C.F.R. § 807.100(b)(2)(ii)(B) (emphasis added). Two points are relevant. First,
7 requesting such clinical studies is a recognized part of 510(k) review. Second, analysis of
8 the clinical data remains comparative – deciding whether the device is substantially
9 equivalent to the predicate. Bard cites no authority for the proposition that clinical
10 studies required during 510(k) review constitute preemptive requirements for purposes of
11 § 360k. Nor does Bard identify the specific clinical study “requirements” that the Court
12 could compare to the various state law duties to determine whether those duties are
13 preempted.

14 Bard also notes that the FDA sought information about the testing and design of its
15 IVC filters. *Id.* at 29-30. But the FDA may request additional information, including
16 information concerning safety and effectiveness, to determine “whether or not the device
17 is substantially equivalent to a [predicate] device[.]” 21 C.F.R. § 807.87(l); *see James*,
18 803 F. Supp. 2d at 947-48. Bard has not shown that the FDA’s request for testing and
19 design information was outside the scope of a normal 510(k) review or sufficient to make
20 it as rigorous as the PMA process.

21 Bard suggests that its EVEREST and Denali clinical studies were similar to the
22 rigorous FDA review in *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004). Doc. 5396
23 at 27-28. But *Horn* involved the PMA process, not 510(k) review, a distinction the
24 Third Circuit found critical: “The primary element distinguishing *Lohr* from the instant
25 case is the fact that the [device] received FDA approval through the rigorous § 360e(c)
26 PMA process, not through the § 510(k) ‘substantial equivalence’ process.” *Id.* at 169.
27 After *Riegel*, there is nothing remarkable about the conclusion in *Horn* that “the PMA
28 process imposed requirements that were specifically applicable to the [device], and that
triggered preemption under § 360k(a).” *Id.* at 170; *see also Kemp v. Medtronic, Inc.*, 231

1 F.3d 216, 227-28 (6th Cir. 2000) (finding FDA approval of a PMA supplement to be a
2 “specific federal requirement applicable to the device”).

3 What is more, the heart pump at issue in *Horn* took nearly twenty years to receive
4 FDA approval. 376 F.3d at 169-70. The device underwent ten years of live animal and
5 human cadaver studies before it was granted an investigational device exemption (“IDE”)
6 by the FDA in order to permit human clinical trials. *Id.* at 169. The manufacturer then
7 conducted seven years of clinical studies at hospitals, during which it submitted 90
8 supplements to the FDA. *Id.* The FDA approved the PMA application only after
9 extensive review that spanned three years and included a substantial number of
10 amendments and responses to FDA questions. *Id.* at 170. This process was clearly more
11 rigorous than the 510(k) review of the Bard IVC filters.

12 Bard cites *Kemp*, 231 F.3d at 227, for the proposition that the IDE clinical trials
13 for the G2 and Denali filters are device-specific and therefore preemptive. Doc. 5396
14 at 25-26; *see also Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1097 (6th Cir.
15 1997) (regulations governing investigational devices are device-specific); *Parks v.*
16 *Howmedica Osteonics Corp.*, No. 8:15-cv-0075-MSS-MAP, 2016 WL 7220707, at *7
17 (M.D. Fla. Mar. 11, 2016) (IDE approval process is device-specific). But as Plaintiffs
18 correctly note, the G2 and Denali filters were given 510(k) clearance before completion
19 of their respective IDE clinical studies. Doc. 7369 at 28. Moreover, Bard fails to explain
20 how IDE clinical studies conducted as part of the 510(k) substantial equivalence review
21 impose requirements for purposes of § 360k. In other words, even if the FDA required
22 IDE clinical studies, Bard does not describe any resulting § 360k “requirements” that
23 would preempt Plaintiffs’ state law claims. *See Oja v. Howmedica, Inc.*, 111 F.3d 782,
24 787-89 (10th Cir. 1997) (rejecting hip implant manufacturer’s arguments that discussions
25 with the FDA to obtain 510(k) clearance including IDE clinical study of cement-less use
26 constituted a specific requirement under *Lohr*).¹⁰

27
28 ¹⁰ Bard notes in its reply that clinical trials are required as part of the PMA
process. Doc. 7828 at 12 (citing *Scovil v. Medtronic, Inc.*, 995 F. Supp. 2d 1082, 1093
(D. Ariz. 2014)). True, but the rigorous PMA process requires more than clinical trials,

c. Labelling and Other Requirements.

Bard argues that, pursuant 21 U.S.C. § 807.87(e), the FDA required proposed labeling for each Bard IVC filter. Doc. 5396 at 28. But proposed labeling is required for every 501(k) submission. Section 807.87 simply describes the information that “[e]ach premarket notification shall contain[.]” These are “federal . . . labeling requirements applicable across the board to almost all medical devices” – requirements which do not preempt state common law claims. *Riegel*, 552 U.S. at 322. They are not like the device- and disease-specific labelling regulation at issue in *Papike*. 107 F.3d at 739-40.

Bard contends that the FDA reviewed and made specific changes to its labels, including adding language regarding bariatric patients and off-label use for the G2 filter and language regarding potential nickel leaching for the Meridian and Denali filters. Doc. 5396 at 28-29. But these changes did not preclude Bard from strengthening its warnings about the risks posed by filter migration, fractures, and perforation. The FDA allows – and in fact encourages – medical device manufactures to “monitor device usage and promptly revise the warning and precautions section [of a label] based on use experience.” Doc. 5398 ¶ 38, Ex. G at 11.

Bards notes that the FDA has issued post-SMDA design controls and “good manufacturing” rules, and that these procedures were applied to Bard filters. Doc. 5396 at 22 (citing 21 C.F.R. §820.30; *Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation*, 61 Fed. Reg. 52615 (FDA Oct. 7, 1996)). But Bard fails to explain how these generally applicable rules constitute filter-specific requirements that would preempt Plaintiffs’ state law claims.¹¹

see Scovil, 995 F. Supp. 2d at 1088-89, and Bard has not shown that the two IDE clinical trials in this case reflect the rigor that makes FDA premarket approval preemptive.

¹¹ Bard notes that the FDA has itself indicated that special controls are “regulatory requirements for class II devices.” Doc. 5396 at 20 n.16 (citing *FDA Medical Devices, Regulatory Controls*, <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm> (last updated June 26, 2014)). Yet Bard cites no legal authority showing that this statement by the agency is controlling for purposes of preemption. *See Wyeth*, 555 U.S. at 556 (giving no deference to the FDA’s mere assertion that state law is preempted where it had enacted no regulation to this effect).

1 Finally, Bard has submitted more than 800 factual paragraphs to illustrate its
2 extensive communications with the FDA concerning the seven generations of filters at
3 issue in this case. Doc. 5398. But the Court agrees with Plaintiffs' suggestion that these
4 communications merely reflect the back-and-forth of 510(k) review. *See* Doc. 7369
5 at 25-29. The FDA invoked its regulatory power to require additional information from
6 Bard as a condition for clearance. *See* 21 U.S.C. § 807.87(l). The mere volume of these
7 communications does not show that the FDA's review imposed specific requirements on
8 Bard filters or departed from the 510(k) substantial equivalence standard.¹²

9 **d. *Papike* and *Degelmann* Are Distinguishable.**

10 Bard cites other cases in support of their argument, but the Court finds them
11 distinguishable. *Papike* involved various claims under California law based on injuries
12 the plaintiff sustained when she contracted Toxic Shock Syndrome ("TSS") while using
13 Tampax tampons. 107 F.3d at 738. The Ninth Circuit found the state failure-to-warn
14 claim preempted under § 360k, but not the state claims for negligence, design defect, and
15 breach of warranties. *Id.* at 738, 742-44. Although tampons are Class II devices subject
16 to special controls, *see id.* at 739, this was not the reason for preemption. Rather, *Papike*
17 found that the FDA had promulgated a device-specific regulation "mandating the specific
18 substantive content of the TSS warnings on tampon boxes[.]" *Id.* at 740. The regulation
19 was "not only device-specific (tampons), but also disease-specific (TSS)." *Id.* "This fact
20 distinguish[ed] *Papike*'s case from prior relevant MDA preemption cases, including
21 [*Lohr*]." *Id.*; *see also Rasheed v. Church & Dwight Co.*, No. 5:11CV80, 2012 WL
22 262619, at *7-8 (E.D. Tex. Jan. 12, 2012) (finding failure-to-warn claim preempted
23
24

25 ¹² Bard asserts that its more than 800 paragraphs of facts are both material and
26 undisputed, and that "there is no genuine issue to be tried." Doc. 5398 at 1. But as
27 Plaintiffs correctly note, Bard's statement includes many documents and communications
28 that are not central to the issues in this case – whether the 510(k) review imposed device-
specific requirements. And the sheer volume of the submission proves nothing.
"Lawyers are tasked with bringing clarity out of chaos, and voluminous filings rarely do
that." *State Compensation Ins. Fund v. Drobot*, No. CV 13-0956 AG, 2016 WL
6661338, at *1 (C.D. Cal. Aug. 10, 2016).

1 where the FDA had issued a specific regulation governing labels for condoms under the
2 same rule subpart as tampons). Bard cites no similar regulation in this case.

3 Bard's reliance on *Degelmann v. Advanced Medical Optics Inc.*, 659 F.3d 835 (9th
4 Cir. 2011), fares no better. *Degelmann* has been vacated by the Ninth Circuit. *See*
5 *Placencia*, 2012 WL 5877624, at *5 n.3. Moreover, even if *Degelmann* was still good
6 law, it would not control here. Doc. 5396 at 13, 19. *Degelmann* concerned contact lens
7 solution approved through 510(k) review and the plaintiffs' state-law claims that the
8 solution was mislabeled as "disinfecting." 659 F.3d at 840-42. The FDA had issued a
9 guidance document containing special controls that "mandate" specific stand-alone
10 performance criteria with which manufacturers "must comply" in order to label their
11 contact lens products as a "disinfecting solution." *Id.* at 341-42. The Ninth Circuit found
12 the guidance document to be a specific requirement that the manufacturer undisputedly
13 had met, and held that the state consumer protection and false advertising claims were
14 preempted because they would impose a state requirement in addition to the federal
15 requirements. *Id.* at 842; *see also Tuttle v. CIBA Vision Corp.*, No. 2:05-CV-340 TS,
16 2007 WL 677134, at *2 (D. Utah Mar. 1, 2007) (finding same guidance document to be a
17 requirement because it is comprehensive and "governs the form, content, and
18 requirements for labels on hydrogen peroxide-based solutions").

19 **e. Federal Requirements Conclusion.**

20 The various FDA reviews of Bard filters do appear to have been more extensive
21 than the 510(k) review at issue in *Lohr*. But Bard has not shown that the reviews
22 imposed device-specific requirements as needed for preemption under § 360(k). The
23 "requirements" identified by Bard are either general, non-preemptive regulations or
24 normal parts of the 510(k) substantial equivalence inquiry.

25 **B. State Requirements.**

26 *Lohr* instructs courts to undertake a "careful comparison" between the federal
27 requirements at issue and the allegedly preempted state requirements to determine
28 whether they fall within the preemptive scope of § 360k. 518 U.S. at 500. The state law

1 must be compared to the federal requirements to determine whether the state law
2 establishes requirements “different from, or in addition to,” the federal requirements. 21
3 U.S.C. § 360k(a)(1)(1). But such a comparison is impossible where, as here, no device-
4 specific federal requirements can be ascertained.

5 The claims asserted by Plaintiffs involve the laws of 50 states – laws the Court
6 must apply in this MDL. *See Am. Life Ins.*, 391 F.3d at 911. Plaintiffs assert multiple
7 causes of action, including claims for strict liability, negligence, breach of warranty,
8 misrepresentation, concealment, and consumer fraud. Doc. 303-1. And yet Bard does
9 not discuss the specific law of any particular state. Bard instead summarizes general state
10 law duties and asserts that those duties impose requirements that are preempted by the
11 requirements imposed on its products through the 510(k) reviews. Doc. 5396 at 30. Such
12 conclusory assertions are insufficient to meet the “careful comparison” required by *Lohr*.
13 For this reason as well, Bard has failed to show that any state law claim is expressly
14 preempted by federal requirements.

15 **V. Implied Preemption.**

16 Because the health and safety of citizens are “‘primarily, and historically, matters
17 of local concern,’ the ‘States traditionally have had great latitude under their police
18 powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all
19 persons.’” *Lohr*, 518 U.S. at 475 (internal citations omitted). Thus, this case presents a
20 classic example of Congress legislating in a field – public health and safety – historically
21 occupied by state police powers. For purposes of implied preemption, therefore, the
22 Court begins with a presumption that state laws are not superseded by the federal statute,
23 a presumption that can be overcome only if preemption “‘was the clear and manifest
24 purpose of Congress.’” *Id.* (citation omitted).

25 Bard contends that Plaintiffs’ state law claims are impliedly preempted because it
26 is impossible for Bard to do under federal law what the state laws require. Doc. 5396
27 at 32-34. The Court does not agree.

1 Bard relies on two Supreme Court cases that involved the FDCA’s labeling
2 requirements for generic prescription drugs, *PLIVA, Inc. v. Mensing*, 564 U.S. 604
3 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, — U.S. —, 133 S.Ct. 2466 (2013).
4 Under the FDCA, a manufacturer can obtain FDA approval to market a drug only by
5 submitting a new-drug application (“NDA”) that is similar to the comprehensive PMA
6 application. 21 U.S.C. § 355(a)-(b); *see Bartlett*, 133 S. Ct. at 2471 (noting that the
7 “process of submitting an NDA is both onerous and lengthy”). The FDA’s approval of
8 an NDA includes the approval of the exact text of the proposed label. 21 U.S.C.
9 § 355(d). Generally speaking, a manufacturer may change a drug label only after the
10 FDA approves a supplemental NDA. *See Wyeth*, 555 U.S. at 568. Manufacturers
11 essentially are prohibited from making any change to a generic drug label because the
12 label must at all times be the same as the label of the corresponding brand-name drug.
13 21 U.S.C. § 314.150(b).

14 In *Mensing* and *Bartlett*, the Supreme Court found state law failure-to-warn claims
15 preempted by the FDCA because it was impossible under federal law for the
16 manufacturers to do what state law required. *Mensing*, 564 U.S. at 618; *Bartlett*, 133 S.
17 Ct. at 2476-78. As the Court explained: “it was impossible for the [m]anufacturers to
18 comply with both their state-law duty to change the label and their federal law duty to
19 keep the label the same.” *Mensing*, 564 U.S. at 618. “Federal law require[d] a very
20 specific label for [the drug], and state law [forbade] the use of that label.” *Bartlett*, 133
21 S. Ct. at 2479.

22 Bard has identified no similar conflict in this case. Bard asserts that it is
23 prohibited from making changes to their filters without FDA approval, but changing a
24 product is quite different from changing a label. FDA regulations understandably
25 provide that FDA clearance is required when a manufacturer’s product “is about to be
26 significantly changed or modified in design, components, method of manufacture, or
27 intended use.” 21 C.F.R. § 807.81(a)(3). The Court does not find such a change
28 comparable to the label changes at issue in *Mensing* and *Bartlett*.

1 Bard also asserts that the FDA prohibits it from making unilateral labeling changes
2 that significantly impact safety and effectiveness without first submitting a new 510(k)
3 notification. Doc. 5396 at 33. In support, Bard cites to an FDA guidance document on
4 when 510(k) submissions are required. *Id.*; Doc. 5398, ¶ 38. The most relevant part of
5 this guidance document for purposes of Plaintiffs’ failure-to-warn claims would seem to
6 be the section on changes in warnings or precautions. That section reads as follows:

7 In order to facilitate a continuous upgrading in device labelling,
8 manufacturers should monitor device usage and promptly revise the
9 warning and precautions section based on use experience. Events that
10 precipitate changes of this type are routinely reported under the medical
11 device reporting regulation. 510(k)s for such labelling changes are
12 generally unnecessary however, manufacturer’s [sic] are encouraged to
discuss these situations with [the FDA’s Center for Devices and
Radiological Health].

13 Doc. 5398, Ex. G at 11. This guidance clearly does not prohibit Bard from making
14 warning changes without FDA approval.¹³

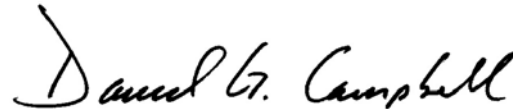
15 “Impossibility pre-emption is a demanding defense.” *Wyeth*, 555 U.S. at 573.
16 Bard has failed to show that it is impossible to make any labeling changes that may be
17 required by state law. Indeed, Bard acknowledges that the FDA previously has cleared
18 labeling changes to Bard IVC filters and in one instance found that no 510(k) was
19 needed. Doc. 5396 at 33. Bard’s impossibility preemption defense is without merit. *See*
20 *Wyeth*, 555 at 571 (“[A]bsent clear evidence that the FDA would not have approved a
21 change to [the drug’s] label, we will not conclude that it was impossible for Wyeth to
22 comply with both federal and state requirements.”); *Mullins v. Ethicon, Inc.*, 147 F. Supp.
23 3d 478, 480-85 (S.D. W. Va. 2015) (rejecting impossibility preemption given “Congress’
24 purpose in enacting the 510(k) provision and the absence of any actual conflict between

25
26 ¹³ The guidance document recently has been superseded. *See* FDA, *Deciding*
27 *When to Submit a 510(k) for a Change to an Existing Device, Guidance for Industry and*
28 *FDA Staff* (Oct. 25, 2017), available at <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514771.pdf> (last visited Nov. 16, 2017). The new guidance document also allows for changes in warnings without a 510(k) submission. *See id.* at 22. Moreover, both documents make clear that they are meant to provide guidance only and do not bind the FDA or the regulated industry.

1 state and federal law”). Bard has also failed to overcome the presumption against
2 preemption that applies to its implied preemption argument.

3 **IT IS ORDERED** that Defendants’ motion for summary judgment regarding
4 preemption (Doc. 5396) is **denied**.

5 Dated this 22nd day of November, 2017.

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David G. Campbell
United States District Judge
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1 **WO**

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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**
8

9 IN RE: Bard IVC Filters Products Liability
10 Litigation,
11 _____

12 Sherr-Una Booker, an individual,
13 Plaintiff,

14 v.

15 C. R. Bard, Inc., a New Jersey corporation;
16 and Bard Peripheral Vascular, Inc., an
17 Arizona corporation,
18 Defendants.
19 _____

No. MDL 15-02641-PHX DGC

No. CV-16-00474-PHX-DGC

ORDER

20 This multidistrict litigation proceeding (“MDL”) involves thousands of personal
21 injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular,
22 Inc. (collectively, “Bard”). Bard manufactures and markets medical devices, including
23 inferior vena cava (“IVC”) filters. The MDL Plaintiffs have received implants of Bard
24 IVC filters and claim that they are defective and have caused Plaintiffs to suffer serious
25 injury or death. Plaintiffs assert numerous state law claims and seek both compensatory
26 and punitive damages.

27 One of the MDL cases is brought by Plaintiff Sherr-Una Booker, who had a Bard
28 filter implanted ten years ago. Plaintiff’s case has been selected as one of several

1 bellwether cases and is set for trial in March 2018. Defendants have filed a motion for
2 partial summary judgment on Plaintiff's claims. Doc. 7456. The motion is fully briefed,
3 and the Court heard oral arguments on November 17, 2017. For reasons set forth below,
4 the Court will grant the motion in part and deny it in part.¹

5 **I. Factual Background.**

6 [The factual background section of this order has been redacted because it sets
7 forth Plaintiff's personal medical information protected from public disclosure under the
8 provisions of HIPPA and orders sealing documents in this case. See Doc. 7787. An
9 unredacted version of this order has been filed under seal. See Doc. 8873.]

10 **II. Plaintiff's Claims.**

11 The Court was assigned this MDL in August 2015. Doc. 1. Three months later,
12 the MDL Plaintiffs filed a long-form master complaint that asserts seventeen causes of
13 action. Doc. 303-1. The master complaint alleges that Bard filters, including the G2,
14 were negligently designed and manufactured and are more dangerous than other IVC
15 filters. The complaint further alleges that Defendants concealed adverse information and
16 otherwise failed to warn about increased risks posed by Bard filters. Defendants dispute
17 the allegations of concealment and high risk levels, contending that complication rates
18 associated with Bard filters are low and comparable to those of other IVC filters.

19 In her short-form individual complaint filed on February 22, 2016, Plaintiff asserts
20 the following claims under Georgia law: manufacturing defects (Master Complaint
21 Counts I and V), failure to warn (Counts II and VII), design defects (Counts III and IV),
22 failure to recall or retrofit (Count VI), misrepresentation (Counts VIII and XII),
23 negligence per se (Count IX), breach of warranties (Counts X and XI), and punitive
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27 ¹ Defendants' motion redacts information concerning Plaintiff's personal medical
28 history. Defendants have filed a sealed unredacted version of the motion. Doc. 7460.
The Court will cite to this unredacted document in addressing Defendants' summary
judgment arguments.

1 damages. Doc. 1, CV-16-00474-PHX-DGC. Plaintiff agreed not to pursue the breach of
2 warranty claims before the present motion was filed. Doc. 7460 at 2 n.1.²

3 Defendants seek summary judgment on all claims other than design defects. *Id.*
4 at 1. In her response to Defendants' motion, Plaintiff concedes the insufficiency of her
5 manufacturing defect and failure to recall or retrofit claims. Doc. 8167 at 2 n.1. The
6 Court will grant summary judgment on these claims and the breach of warranty claims.

7 The remaining claims on which Defendants seek summary judgment are failure to
8 warn, misrepresentation, negligence per se, and punitive damages. The Court will deny
9 summary judgment on the failure to warn and punitive damages claims and grant
10 summary judgment on the claims for misrepresentation and negligence per se.

11 **III. Summary Judgment Standard.**

12 A party seeking summary judgment "bears the initial responsibility of informing
13 the court of the basis for its motion, and identifying those portions of [the record] which
14 it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v.*
15 *Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the moving party
16 shows that there is no genuine dispute as to any material fact and the movant is entitled to
17 judgment as a matter of law. Fed. R. Civ. P. 56(a). Only disputes over facts that might
18 affect the outcome of the suit will preclude the entry of summary judgment, and the
19 disputed evidence must be "such that a reasonable jury could return a verdict for the
20 nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The
21 evidence of the nonmoving party, however, is to be believed, and all justifiable inferences
22 drawn in that party's favor because "[c]redibility determinations, the weighing of
23 evidence, and the drawing of inferences from the facts are jury functions[.]" *Id.* at 255.

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27 ² Plaintiff does not assert claims for fraudulent concealment (Master Complaint
28 Count XIII), consumer fraud and unfair trade practices (Count XIV), loss of consortium
(Count XV), wrongful death (Count XVI), or survival claims (Count XVII). *See id.*;
Doc. 303-1 ¶¶ 267-338.

1 **IV. Failure to Warn (Counts II and VII).**

2 The parties agree that Georgia law applies because the alleged injuries occurred in
3 Georgia and Plaintiff lived there when the complaint was filed. Doc. 7460 at 6. To
4 establish a failure to warn claim under Georgia law, “the plaintiff must show the
5 defendant had a duty to warn, the defendant breached that duty and the breach was the
6 proximate cause of the plaintiff’s injury.” *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d
7 1351, 1362 (N.D. Ga. 1999). “[A] manufacturer has a duty to warn of nonobvious
8 foreseeable dangers from the normal use of its product.” *Thornton v. E.I Du Pont de*
9 *Nemours & Co.*, 22 F.3d 284, 289 (11th Cir. 1994) (citations omitted). The duty to warn
10 arises “whenever the manufacturer knows or reasonably should know of the danger
11 arising from the use of its product.” *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga.
12 1994). The duty generally is “breached by (1) failing to adequately communicate the
13 warning to the ultimate user or (2) failing to provide an adequate warning of the
14 product’s potential risks.” *Thornton*, 22 F.3d at 289.

15 In cases involving prescription drugs and medical devices, Georgia applies the
16 “learned intermediary” doctrine. Under this doctrine, the manufacturer has no “duty to
17 warn the patient of the dangers involved with the product, but instead has a duty to warn
18 the patient’s doctor, who acts as a learned intermediary between the patient and
19 manufacturer.” *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003) (citing
20 *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1279-80 (11th Cir. 2002)). The manufacturer’s
21 warnings to the physician, however, “must be adequate or reasonable under the
22 circumstances of the case.” *Id.*

23 In this case, the G2 filter’s Instructions for Use (“IFU”) were available to Dr.
24 D’Ayala when he decided to implant the filter in Plaintiff, but he did not have
25 information about any increased risks associated with Bard filters. Doc. 7462-2 at 5-6.
26 Plaintiff alleges that the instructions Bard provided failed to adequately warn about the
27 device’s known defects and high complication rates, including the filter’s propensity to
28 tilt, fracture, and perforate the IVC. *See* Doc. 303-1 ¶¶ 174-78, 211-16. Plaintiff claims

1 that this failure to warn constitutes a breach of Bard's duty to adequately warn of the
2 dangers presented by its IVC filters, and proximately caused her injuries. *Id.* ¶¶ 177-81,
3 215-17. Plaintiff asserts strict liability and negligence claims for the alleged failure to
4 warn. *Id.* ¶¶ 171-81, 202-09; *see* Doc. 1 at 3, CV-16-00474-PHX-DGC.

5 Defendants contend that the warnings contained in the IFU were adequate as a
6 matter of law because they included the risks of filter movement, fracture, and
7 perforation – the very complications Plaintiff experienced. Doc. 7460 at 9-11.
8 Defendants further contend that proximate cause is lacking because Dr. D'Ayala
9 implanted the G2 filter with knowledge of its potential risks, and there is no evidence that
10 additional warnings would have made him choose a different filter or treatment. *Id.* at
11 11-12. For purposes of summary judgment, Defendants do not dispute that Plaintiff has
12 presented evidence that Bard knew its IVC filters had complication rates higher than
13 other filters at the time Plaintiff was implanted with the G2 filter. *See* Doc. 8167 at 4-7.

14 **A. Adequacy of the Warnings.**

15 The IFU for the G2 filter included the following warnings under the bold heading
16 of "Potential Complications":

- 17 • Movement or migration of the filter is a known complication of vena cava
18 filters. This may be caused by placement in IVCs with diameters
19 exceeding the appropriate labeled dimensions specified in the IFU.
20 Migration of filters to the heart or lungs have also been reported in
21 association with improper deployment, deployment into clots and/or
22 dislodgment due to large clot burdens.
- 23 • Filter fracture is a known complication of vena cava filters. There have
24 been reports of embolization of vena cava filter fragments resulting in
25 retrieval of the fragment using endovascular and/or surgical techniques.
26 Most cases of filter fracture, however, have been reported without any
27 adverse clinical sequelae.
- 28 • Perforation or other acute or chronic damage of the IVC wall.
- All of the above complications have been associated with serious adverse
events such as medical intervention and/or death. There have been reports
of complications, including death, associated with the use of vena cava

1 filters in morbidly obese patients. The risk/benefit ratio of any of these
2 complications should be weighed against the inherent risk/benefit ratio for a
3 patient who is at risk of pulmonary embolism without intervention.

4 Doc. 7457-1 at 2.

5 Plaintiff concedes that the IFU warned about G2 filters tilting, fracturing, and
6 perforating the IVC, but notes that these complications exist for all IVC filters.
7 Doc. 8167 at 13. Plaintiff argues that the warnings were inadequate because they did not
8 include risk rates or disclose that the risks associated with the G2 filter were higher than
9 those of other filters, including Bard's own Simon Nitinol filter ("SNF"). *Id.* at 12.

10 Framing the issue as one of duty, Defendants contend that Georgia law imposes no
11 duty on a manufacturer to provide comparative complication rates for its product and
12 those of competitors. Doc. 7460 at 10 n.4; *see* Doc. 7351 at 9-10. Plaintiff counters that
13 the issue is one of breach, not duty, and that there is a triable issue as to whether
14 Defendants' failure to warn about increased risks constitutes a breach of their duty to
15 provide an adequate warning.

16 This very issue was addressed in *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195,
17 2013 WL 5700513 (S.D. W. Va. Oct. 18, 2003). *Cisson*, which applied Georgia law,
18 found that "[a]lthough Bard frames the issue as one of duty, it actually relates to whether
19 Bard's warnings were adequate, which is a question of breach." *Id.* at *7. The Court
20 agrees with this conclusion. Under Georgia law, a duty to warn arises "whenever the
21 manufacturer knows or reasonably should know of the danger arising from the use of its
22 product." *Batten*, 450 S.E.2d at 211. Defendants cite no authority to suggest that this
23 duty arises only on a fact-by-fact basis. The duty arises when dangers are known or
24 reasonably known, and the factual detail that must then be disclosed is then addressed in
25 the adequacy of the disclosure. The duty to warn is breached by "failing to provide an
26 *adequate warning of the product's potential risks.*" *Thornton*, 22 F.3d at 289 (emphasis
27 added). After concluding that the question was one of breach, *Cisson* denied judgment
28 on the failure to warn claim, noting that other courts have held that a failure to warn

1 about the rate or severity of potential injuries raises a jury question over the adequacy of
2 the warnings. 2013 WL 5700513 at *7.

3 The exact warning at issue in this case was considered recently in *Cason v. C. R.*
4 *Bard, Inc.*, No. 1:12-CV-1288-HMS, 2015 WL 9913809 (N.D. Ga. Feb. 9, 2015). In
5 *Cason*, as in this case, there was evidence that the G2 filter has a greater propensity to
6 migrate, fracture, and perforate the IVC, and that Bard had knowledge of such increased
7 risks at all relevant times. *Id.* at *4-5. Given this evidence, and the fact that Bard did not
8 warn the plaintiff's doctor about the increased risks, *Cason* concluded that a jury
9 reasonably could find that "the IFU did not contain an adequate warning regarding the G2
10 Filter." *Id.* at *5. The Court finds this ruling by a Georgia-based federal judge, applying
11 Georgia law, to be highly persuasive. Other cases applying Georgia law have reached
12 similar conclusions. *See Cisson*, 2013 WL 5700513, at *8 (rejecting Bard's argument
13 that warnings were adequate as a matter of law because the IFU identified as a possible
14 adverse reaction each of the complications the plaintiff experienced); *In re Mentor Corp.*
15 *ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1378 (M.D. Ga.
16 2010) (rejecting similar argument where the product at issue had a greater propensity to
17 cause complications and was associated with more severe complications than other
18 products); *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1219-20 (11th Cir. 1999) (denying
19 summary judgment on failure to warn claim where Ford's internal documents showed
20 that the Bronco II had a rollover fatality rate more than three times that of other SUVs
21 and the vehicle was rated last in government stability tests).³

22 The Court notes that some of the warnings in the G2 filter's IFU are limited in
23 scope. Although filter movement and migration are identified as known complications,
24

25 ³ Defendants asserted at oral argument that *Cisson* and *Cason* were causation cases
26 that did not address duty and breach. To the contrary, *Cisson* made clear that "Bard had a
27 duty to warn about 'any potential dangers that may result' from use of the product[.]" and
28 that the adequacy of Bard's warnings was a question of breach, not duty. 2013 WL 5700513,
at *6-7 (citation omitted). Similarly, *Cason* discussed at length Bard's arguments that it had
no duty to warn about increased risks and that its warnings were adequate as a matter of law.
2015 WL 9913809, at *3-6. The issue of causation was discussed only briefly in the last
paragraph addressing the failure to warn claim. *Id.* at *6.

1 the IFU states that “[t]his may be caused by placement in IVCs with diameters exceeding
2 the appropriate labeled dimensions specified in the IFU.” Doc. 7457 ¶ 5. The IFU notes
3 that migration of filters to the heart or lungs has been reported, but only “in association
4 with improper deployment, deployment into clots and/or dislodgment due to large clot
5 burdens.” *Id.* The IFU discloses reports of serious adverse events associated with the use
6 of IVC filters, including death, but only in “morbidly obese patients.” *Id.* With respect
7 to filter fracture, the IFU states that most cases had “been reported without any adverse
8 clinical sequelae.” *Id.* Plaintiff has presented evidence to the contrary, along with other
9 evidence from which a jury reasonably could find that the warnings contained in the IFU
10 were not adequate. *See Cisson*, 2013 WL 5700513, at *8 (denying motion for judgment
11 as a matter of law where the plaintiff presented evidence that Bard’s IFU “downplayed
12 risks by stating that ‘potential adverse reactions are those typically associated with
13 surgically implantable materials’”).

14 Defendants argue that they cannot be held liable for failure to warn because the
15 complications Plaintiff experienced – filter tilting, fracture, and perforation – were well
16 documented and known to medical professionals, including Dr. D’Ayala. Doc. 7460
17 at 10. But this argument misses the mark. As Defendants themselves note, Plaintiff
18 claims that the general warning about complications associated with all IVC filters was
19 inadequate given the G2 filter’s *higher* complication rates. *Id.* at 10 n.4. Plaintiff
20 presents evidence that the G2 filter involved substantially greater risks of failure than
21 competitor filters and even Bard’s own SNF filter, and that evidence must be accepted as
22 true for purposes of this summary judgment motion.⁴

23 Defendants state that including warnings about comparative risk rates “is almost
24 certainly precluded by FDA regulations,” but they cite no specific regulation in support
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26 ⁴ Defendants cite *Presto v. Sandoz Pharmaceuticals Corp.*, 487 S.E.2d 70, 73 (Ga.
27 Ct. App. 1997), for the proposition that warning the physician about a product’s potential
28 risks is sufficient. Doc. 7460 at 10. The warning, however, must be adequate or
reasonable under the circumstances. *See McCombs*, 587 S.E.2d at 595. *Presto* is
inapposite because the plaintiffs in that case “ma[de] no argument that the warning given
[the doctor] was inadequate.” 487 S.E.2d at 73.

1 of this assertion. Doc. 8574 at 4. The opinion of Defendants’ regulatory expert in this
2 regard creates a fact issue for the jury. Defendants’ reliance on cases involving
3 prescription drugs is misplaced because those cases concern a specific FDA regulation
4 not applicable to medical devices such as the G2 filter. *See* 21 C.F.R. § 201.57(c)(7)
5 (providing that “any claim comparing [a prescription drug] with other drugs in terms of
6 frequency, severity, or character of adverse reactions must be based on adequate and
7 well-controlled studies”).

8 Defendants contend that Georgia law does not require a manufacturer to provide
9 comparative rates of complications for its products. Doc. 7460 at 10 n.4; Doc. 7351
10 at 9-10 (citing *Dixie Grp., Inc. v. Shaw Indus. Grp., Inc.*, 693 S.E.2d 888, 892 (Ga. Ct.
11 App. 2010); *Hoffman v. AC & S, Inc.*, 548 S.E.2d 379, 382 (Ga. Ct. App. 2001)). But the
12 cases cited by Defendants concern very different questions: whether a manufacturer can
13 be liable for injuries caused by modifications another party made to its product, *Dixie*
14 *Grp.*, 693 S.E.2d at 892, and whether a plaintiff must show that it was the defendant’s
15 asbestos product – as opposed to an asbestos products generally – that caused her
16 mesothelioma, *Hoffman*, 548 S.E.2d at 382. “Nothing in these cases suggests that a
17 manufacturer’s warning is adequate even if it fails to warn that the product is
18 significantly more dangerous than other similar products on the market.” *Cason*, 2015
19 WL 9913809, at *5.

20 “The general rule in Georgia is that the adequacy of the warning is an issue for the
21 jury [unless] . . . the facts support only one conclusion, that is, the warning and its
22 communication were adequate.” *Thornton*, 22 F.3d at 289 (citations omitted). In this
23 case, there are facts from which a jury reasonably could conclude that the warnings
24 contained in the IFU were not “adequate or reasonable under the circumstances of the
25 case.” *McCombs*, 587 S.E.2d at 595. The “question that must be answered by the fact
26 finder is whether the warning given was sufficient or was inadequate because it did not
27 ‘provide a complete disclosure of the existence and extent of the risk involved.’”
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1 *Watkins*, 190 F.3d at 1220 (quoting *Thornton*, 22 F.3d at 289); *see Cason*, 2015 WL
2 9913809, at *4-5; *Cisson*, 2013 WL 5700513, at *7-8.

3 The Court is not holding, as a matter of Georgia law, that manufacturers must
4 always disclose how the risks of their product compare to the risks of other products. But
5 presumably there is a point where the risks of a product so depart from the norm that a
6 failure to disclose them constitutes an inadequate warning. Whether that point was
7 reached in this case will be for the jury to decide. *See Cason*, 2015 WL 99913809, at *6
8 (the question “is not whether [D]efendants are able to provide completely up-to-date
9 failure rate comparisons but whether, prior to [Plaintiff’s] surgery, they had sufficient
10 information such that they knew or should have known that use of the G2 Filter involved
11 a significantly increased risk of complications as compared to other IVC filters.”).

12 Finally, Defendants contend that summary judgment is warranted because Plaintiff
13 never identifies the precise information the G2 warnings should have contained.
14 Doc. 7460 at 7 (citing *Nolley v. Greenlee Textron, Inc.*, No. 1:06-CV-228-MHS, 2007
15 WL 5369405, at *7 (N.D. Ga. Dec. 6, 2007)). To the contrary, Plaintiff makes clear that
16 the IFU should have disclosed that the “risks associated with Bard’s devices were higher
17 than those of competitor devices or the SNF.” Doc. 8167 at 12. The jurors in this case,
18 unlike in *Nolley*, will be presented with proposed warnings and will have a means by
19 which to determine whether the actual warnings were adequate. The Court will consider
20 the parties’ proposed jury instructions on the issue of inadequate warnings.

21 **B. Causation.**

22 To prevail on a failure to warn claim, a plaintiff must show that the deficient
23 warning caused her injury. *See Wheat*, 46 F. Supp. at 1362. “Where a learned
24 intermediary has actual knowledge of the substance of the alleged warning and would
25 have taken the same course of action even with the information the plaintiff contends
26 should have been provided, courts typically conclude that . . . the causal link is broken
27 and the plaintiff cannot recover.” *Id.* at 1363.

1 Defendants contend that any failure to warn Dr. D'Ayala that IVC filters may tilt,
2 fracture, and perforate the IVC wall was not the proximate cause of Plaintiff's injuries
3 because Dr. D'Ayala was aware of these risks when he implanted the G2 filter in
4 Plaintiff. Doc. 7460 at 11. But as explained above, Plaintiff's position is that Defendants
5 failed to warn Dr. D'Ayala about significantly higher complication rates posed by Bard
6 filters. Doc. 8167 at 12-16. The fact that Dr. D'Ayala knew about the existence of
7 complications for all IVC filters does not preclude a showing of causation.

8 Dr. D'Ayala testified that when he implanted the G2 filter in Plaintiff in June 2007
9 he was not aware of the high number of adverse events associated with Bard's Recovery
10 filter, the predicate device for the G2. Doc. 8169 ¶ 332-33 (Tr. 33:10-34:5). Nor was he
11 aware of certain Bard documents showing higher complication rates in the Recovery
12 device compared to other filters, including Bard's 2004 crisis management plan, the 2004
13 health hazard evaluation, the 2005 migration remedial action plan, and the adverse event
14 reports contained in the FDA's Manufacture and User Facility Device Experience
15 ("MAUDE") database. *Id.* ¶¶ 334-336 (Tr. 34:7-40:2). Dr. D'Ayala testified that this
16 information would have influenced his prescribing habits and he would have liked to
17 have known about the high number of adverse events before implanting the G2 filter in
18 Plaintiff. *Id.* Regarding his decision to use a Bard filter, Dr. D'Ayala stated:

19 With regards to the Bard filter, would I have used a different device if I
20 knew at the time that the Bard filter was not ideal or as good as some of the
21 other implants? The answer would have to be yes. . . . I would have used a
22 different filter if there was a different filter that I knew of that was better, in
terms of its safety profile.

23 *Id.* ¶ 338; Docs. 7462-2 at 3, 8169-1 at 32-33 (Tr. 62:25-63:1-9). Consistent with this
24 testimony, Dr. D'Ayala also stated: "If I knew that one filter was better than another, as I
25 said before, absolutely, I would use it." Doc. 8574-1 at 21 (Tr. 76:25-77:2).

26 Defendants note that Dr. D'Ayala testified that it was "[d]ifficult to say with
27 certainty" whether he would have used a G2 filter in light of internal Bard documents
28 showing higher complication rates because "[it] would depend upon what other filters

1 [they] had at the time and what their problems would have been.” Doc. 7462-2 at 3
2 (Tr. 63:21-25). Dr. D’Ayala also stated that some filter has to be used in treating difficult
3 patients like Plaintiff, and “it becomes a matter of deciding which filter is best[.]” *Id.*
4 (Tr. 70:20-25). Dr. D’Ayala made clear, however, that information about higher
5 complication rates “would have been a very important piece of information to have, as far
6 as making a decision regarding [Plaintiff].” *Id.* at 4 (Tr. 63:25-64:1-3).

7 Defendants assert in their reply brief that Dr. D’Ayala’s testimony about what he
8 may or may not have done constitutes mere conjecture and speculation that is insufficient
9 to establish causation as a matter of law. Doc. 8574 at 9 & n.8. The Court does not
10 agree. Dr. D’Ayala stated that information about higher complication rates would have
11 influenced his decision, and that he would have used a different device had he known the
12 Bard filter was not as good as other available devices. Doc. 8169-1 at 25-28, 32-33.
13 Indeed, Dr. D’Ayala ultimately stopped using Bard filters due to reports of migration and
14 fragmentation in the MAUDE database and medical literature. *Id.* at 22 (Tr. 31:13-25).
15 Although it is true that Dr. D’Ayala also made more equivocal statements during his
16 deposition, Plaintiff must prove her case by a preponderance of the evidence, not with
17 absolute certainty. Construing Dr. D’Ayala’s testimony in Plaintiff’s favor, as required at
18 the summary judgment stage, the Court finds that it creates a question of fact on the issue
19 of causation.

20 Defendants note that Dr. D’Ayala does not rely on a manufacturer’s internal
21 documents when deciding which filter to use because such documents are unreliable.
22 Doc. 8574 at 9. But this says nothing about whether Dr. D’Ayala would have implanted
23 a different filter had Defendants warned about higher complication rates in the IFU for
24 the G2 device or in other public documents. Stated differently, the question is not what
25 Dr. D’Ayala would have done had he been aware of Defendant’s internal documents, but
26 what he would have done had Defendants provided adequate public warnings.

27 Under Georgia law, summary judgment is warranted on the issue of causation only
28 where the physician testifies unequivocally that he would have made the same decision

despite the proposed warning. *See Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010) (doctor provided “explicit, uncontroverted testimony that, even when provided with the most current research and FDA mandated warnings, he still would have prescribed [anti-depressant]”); *Porter v. Eli Lilly & Co.*, No. 1:06-CV-1297-JOF, 2008 WL 544739, at *13 (N.D. Ga. Feb. 25, 2008) (doctor “unequivocally testified that even if he had read the warning that [plaintiff] asserts should have been given, he still would have prescribed [anti-depressant] to the decedent”). Defendants cite no such testimony from Dr. D’Ayala. *See Watkins v. Eli Lilly & Co.*, No. 1:08-CV-1665, 2010 WL 11493785, at *9 (N.D. Ga. Mar. 31, 2010) (denying summary judgment where the defendant failed to “nail[] this matter down” through deposition testimony).

In summary, the Court concludes that Dr. D’Ayala’s testimony “is sufficient evidence of causation at the summary judgment stage, because ‘it can be inferred that [he] would not have implanted the G2 Filter’” had he been warned about its higher complication rates. *Cason*, 2015 WL 9913809, at *6 (quoting *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. CV 2:10-cv-01224, 2013 WL 2431975, at *7 (S.D. W. Va. June 4, 2013)); *see Cisson*, 2013 WL 5700513, at *9-10 (denying summary judgment where there was sufficient evidence for a jury to find that the proposed warnings would have prevented the doctor from implanting a Bard device). The Court will deny summary judgment on Plaintiff’s failure to warn claims.

V. Misrepresentation (Counts VIII and XII).

“In Georgia, the plaintiff must show actual reliance to support both negligent misrepresentation and fraud claims.” *Fanelli v. BMC Software, Inc.*, No. 1:11-cv-00436-JOF, 2013 WL 12190241, at *10 (N.D. Ga. July 29, 2013) (citations omitted). Summary judgment is warranted, Defendants argue, because Plaintiff has presented no evidence showing that either she or Dr. D’Ayala relied on any representation made by Defendants. Docs. 7460 at 7-8 n.3, 8574 at 11. Plaintiff does not address this argument in her response brief (*see* Doc. 8167 at 16-17), and at oral argument stated only that Dr. D’Ayala should have been told about the G2 filter’s higher complication rates.

1 But Plaintiff asserts claims for misrepresentation, not concealment. Doc. 1 at 3-4,
2 CV-16-00474-PHX-DGC. Although Dr. D’Ayala had access to the G2 filter’s IFU at the
3 time of Plaintiff’s surgery (Doc. 7462-2 at 5-6), Plaintiff has pointed to no evidence
4 showing that Dr. D’Ayala relied on the IFU or any other representation made by
5 Defendants. The Court therefore will grant summary judgment on the misrepresentation
6 claims. *See Celotex*, 477 U.S. at 324 (summary judgment warranted where “the
7 nonmoving party has failed to make a sufficient showing on an essential element of her
8 case with respect to which she has the burden of proof”).⁵

9 **VI. Negligence Per Se (Count IX).**

10 “In Georgia, ‘the violation of a statute, ordinance or mandatory regulation that
11 imposes a legal duty for the protection of others constitutes negligence per se.’ *Ashton*
12 *Park Trace Apartments, LLC v. W. Oilfields Supply Co.*, No. 14-CV-4056-MHC, 2015
13 WL 12469074, at *6 (N.D. Ga. July 16, 2015) (citation omitted). This theory of liability
14 is codified in a Georgia statute: “When the law requires a person to perform an act for
15 the benefit of another or to refrain from doing an act which may injure another, although
16 no cause of action is given in express terms, the injured party may recover for the breach
17 of such legal duty if he suffers damage thereby.” Ga. Code Ann. § 51-1-6. Defendants
18 are liable for negligence per se, Plaintiff alleges, because they violated various provisions
19 of the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, and related
20 regulations by misbranding Bard filters, making false and misleading statements about
21 the filters, failing to notify the FDA when the filters were no longer safe and effective,
22 failing to recall the devices, and not maintaining accurate adverse event reports.

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25 ⁵ It also appears that, under Georgia law, there are no misrepresentation claims for
26 products liability distinct from failure to warn claims. *See Gaddy v. Terex Corp.*, 1:14-
27 cv-1928-WSD, 2017 WL 3476318, at *5 (N.D. Ga. May 5, 2017); *Brazil v. Janssen*
28 *Research & Dev. LLC*, 249 F. Supp. 3d 1321, 1340 (N.D. Ga. 2016); *Swicegood v. Pliva,*
Inc., 543 F. Supp. 2d 1351, 1357 (N.D. Ga. 2008). For reasons they did not explain,
however, Defendants withdrew this position at oral argument.

1 Doc. 303-1 ¶ 231.⁶

2 Defendants argue that this claim is impliedly preempted under 21 U.S.C. § 337(a)
3 because no private right of action exists under the FDCA and all proceedings to enforce
4 or restrain violations of the statute must be brought by the FDA. The Court agrees.

5 Plaintiff alleges no violation of any state ordinance, regulation, or statute in
6 support of her negligence per se claim. The master complaint cites statutory provisions
7 of more than 40 states, but Georgia is not one of them (*see* Doc. 303-1 at 56-60), and
8 Plaintiff otherwise does not assert statutory claims for consumer fraud or unfair trade
9 practices (*see* Doc. 1 at 4, CV-16-00474-PHX-DGC). Thus, Plaintiff’s negligence per se
10 claim exists solely because of alleged violations of the FDCA and its implementing
11 regulations. Doc. 303-1 at 56-60.

12 Courts have held that “no private right of action exists for a violation of the
13 FDCA.” *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002). “The
14 FDCA leaves no doubt that it is the Federal Government rather than private litigants who
15 are authorized to file suit for noncompliance with the medical device provisions.”
16 *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 n. 4 (2001). Indeed, § 337(a)
17 expressly provides that “all . . . proceedings for the enforcement, or to restrain violations,
18 of [the FDCA] shall be by and in the name of the United States.” Thus, “a private litigant
19 cannot bring a state-law claim against a defendant when the state-law claim is in
20 substance (even if not in form) a claim for violating the FDCA – that is, when the state
21 claim would not exist if the FDCA did not exist.” *Leonard v. Medtronic, Inc.*, No. 1:10-
22 CV-03787-JEC, 2011 WL 3652311, at *7 (N.D. Ga. Aug. 19, 2011) (citation omitted).

23 In *Buckman*, the Supreme Court held that a state law claim that a defendant made
24 fraudulent statements to the FDA, in violation of FDCA, was impliedly preempted
25 by § 337(a) because the claim “exist[ed] solely by virtue” of FDCA requirements and
26 therefore “would not be relying on traditional state tort law which had predated the

27
28 ⁶ Specifically, Plaintiff alleges violations of 21 U.S.C. §§ 321, 331, 352, and 21
C.F.R. §§ 1.21, 801, 803, 807, 820. *Id.* at 46-48.

1 [FDCA].” 531 U.S. at 353. The same is true here. Plaintiff’s “claim of negligence per
2 se would not exist prior to the enactment of the FDCA . . . because the claim only alleges
3 violation of that law.” *Leonard*, 2011 WL 3652311, at *8. Thus, “as in *Buckman*,
4 Plaintiff’s negligence per se claim (or, more appropriately characterized, [her] negligence
5 claim based solely on violations of the FDA-Imposed Requirements or other FDA
6 regulations) is impliedly preempted by the FDCA.” *Grant v. Corin Grp. PLC*, No. 3:15-
7 CV-169-CAB-BLM, 2016 WL 447523, at *4 (S.D. Cal. Jan. 15, 2016).

8 Plaintiff notes that Georgia common law and § 51-1-6 recognize that laws which
9 do not create a private right of action may nonetheless support a claim for damages.
10 Doc. 8167 at 18-19. While it is true that courts generally have allowed a negligence per
11 se claim based on violation of a federal statute, including those that may not expressly
12 provide for a private right of action, “the plain language of § 337(a) and the *Buckman*
13 decision indicate that, where the FDCA is concerned, such claim fails.” *Dunbar v.*
14 *Medtronic, Inc.*, No. CV 14-01529-RGK AJWX, 2014 WL 3056026, at *6 (C.D. Cal.
15 June 25, 2014). Even if state law recognizes such claims, federal law preempts them.

16 Plaintiff asserts that *Leonard* is inapposite because, unlike Bard IVC filters, the
17 medical device at issue in *Leonard* had been approved by the FDA through the rigorous
18 premarket approval process. Doc. 8167 at 18. But this was not the basis for *Leonard*’s
19 implied preemption finding. *Leonard* found implied preemption because “all
20 proceedings to enforce or restrain violations of the FDCA ‘shall be by and in the name of
21 the United States.’” 2011 WL 3652311, at *7 (quoting § 337(a)). Moreover, preemption
22 under § 337(a) is not limited to devices approved through the premarket approval
23 process. As Defendants note, the device at issue in *Buckman* – like the G2 filter in this
24 case – was cleared for market under 510(k) review. Doc. 8547 at 13.

25 Plaintiff’s reliance on *McClellan v. I-Flow Corp.*, 776 F.3d 1035 (9th Cir. 2015),
26 is misplaced. In that case, the plaintiff’s state law failure-to-warn claim had “little to do
27 with direct regulatory interaction with the FDA.” 776 F.3d at 1041. The Ninth Circuit
28 found that a negligence per se jury instruction therefore would not usurp the FDA’s

1 exclusive enforcement power over the MDA. *Id.* at 1041 & n.6. In this case, by contrast,
2 Plaintiff’s claim exists solely because of alleged FDCA violations and Defendants’
3 interaction with the FDA. The claim clearly is preempted under § 337(a) and *Buckman*.

4 The Court will grant summary judgment on Plaintiff’s negligence per se claim
5 because allowing the claim to go forward would authorize an impermissible action to
6 enforce provisions of the FDCA and its implementing regulations. *See Leonard*, 2011
7 WL 3652311, at *7-8; *Connelly v. St. Jude Med., Inc.*, No. 5:17-cv-02005-EJD, 2017 WL
8 361962, at *5 (N.D. Cal. Aug. 23, 2017) (negligence per se claim preempted where it was
9 “based entirely on violations of the FDCA and its implementing regulations”); *Franklin*
10 *v. Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *8 (D. Colo.
11 May 12, 2010) (“[T]o the extent that Plaintiff seeks to ground her negligence per se and
12 misrepresentation claims on allegations that Defendant violated the FDCA – namely, by
13 selling a misbranded and adulterated product – these claims are impliedly preempted
14 pursuant to 21 U.S.C. § 337(a.)”); *see also Mink v. Smith & Nephew*, 860 F.3d 1319,
15 1330 (11th Cir. 2017) (failure-to-report claim preempted because the duty was owed to
16 the FDA and the “theory of liability is not one that state tort law has traditionally
17 occupied”); *Perez v. Nidek Co.*, 711 F.3d 1109, 1119-20 (9th Cir. 2013) (fraud-by-
18 omission claim “impliedly preempted because it conflicts with the FDCA’s enforcement
19 scheme”).

20 This holding is not inconsistent with the Supreme Court’s decision in *Riegel v.*
21 *Medtronic, Inc.*, 552 U.S. 312 (2008). *Riegel* addressed the scope of 21 U.S.C.
22 § 360k(a), which expressly preempts any state requirement concerning a medical device
23 that “is different from, or in addition to,” a federal requirement relating to the device.
24 *Riegel* held that this provision “does not prevent a State from providing a damages
25 remedy for claims premised on a violation of FDA regulations” where “the state duties in
26 such a case ‘parallel,’ rather than add to, federal requirements.” 552 U.S. at 329; *see*
27 *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) (“Nothing in § 360k denies [a state]

1 the right to provide a traditional damages remedy for violations of common-law duties
2 when those duties parallel federal requirements.”).

3 In this case, however, Plaintiff relies on no parallel state duty in support of her
4 negligence per se claim. The claim cites no Georgia statute. It relies exclusively on
5 alleged violations of the FDCA and its implementing regulations. Plaintiff is not suing
6 under state law for conduct that happens to violate the FDCA, but instead is suing solely
7 “because the conduct violates the FDCA.” *Perez*, 711 F.3d at 1120 (emphasis in
8 original). Such claims are impliedly preempted under *Buckman* and § 337(a). *See id.*

9 **VII. Punitive Damages.**

10 Under Georgia law, punitive damages may be awarded only where “it is shown by
11 clear and convincing evidence that the defendant’s actions showed willful misconduct,
12 malice, fraud, wantonness, oppression, or that entire want of care which would raise the
13 presumption of conscious indifference to consequences.” Ga. Code Ann. § 51-12-5.1(b).
14 Defendants contend that punitive damages are not warranted because there is no evidence
15 they acted with the requisite state of mind and they otherwise complied with all
16 applicable FDA regulations. Doc. 7460 at 14-15. “Compliance with federal regulations,
17 however, is not sufficient to automatically preclude an award of punitive damages.”
18 *Cason*, 2015 WL 9913809, at *6 (citing *Cisson*, 2013 WL 5700513, at *11-12). This is
19 particularly true where, as in this case, the device at issue was cleared by the FDA under
20 510(k) review which focuses primarily on equivalence with other products, not safety.
21 *Cisson*, 2013 WL 5700513, at *12.

22 Plaintiff claims that Defendants’ actions constitute an entire want of care that
23 shows a “conscious indifference” to the dangerous consequences posed by the Recovery
24 filter and its successor, the G2. Doc. 8167 at 19-22. Plaintiff argues that a jury
25 reasonably could award punitive damages because there is evidence that Defendants
26 knew the G2 filter was less safe than the SNF and was failing at a higher rate than
27 competitor devices, and yet never identified the root cause of the failures, provided
28

1 adequate warnings, recalled or suspended sales of Bard filters, or implemented known
2 design improvements to address filter migration and perforation. *Id.* at 22.

3 Under the conscious indifference standard, “[n]umerous Georgia cases have held
4 that punitive damages are available where a manufacturer knows that its product is
5 potentially dangerous and chooses to do *nothing* to make it safer or to warn consumers.”
6 *Cisson*, 2013 WL 5700513, at *13 (citations omitted) (emphasis in original). Plaintiff has
7 presented evidence that the Recovery filter had failed internal tests and performed worse
8 than the SNF and competitor devices, and that Bard did not have a full understanding of
9 the filter’s design elements before full market release. Doc. 7950 ¶¶ 29, 33-39. Bard
10 began receiving complaints of filter migration and fractures in 2003, and reports of
11 failures resulting in death by April 2004. *Id.* ¶¶ 28, 31. Rather than warning physicians
12 or recalling the filter, Plaintiff alleges that Bard hired a public relations firm to prepare a
13 “Crisis Management Plan” and help Bard “manage controversial or negative stories
14 surrounding the Recovery [filter].” *Id.* ¶ 44, Ex. 38. Bard’s bottom line message to the
15 public was: “good filter, severe case, bad outcome, deep regret.” *Id.* ¶ 45. Bard viewed
16 this as a “simple story” to be repeated “again and again.” *Id.* Significantly, Bard found
17 “[c]omparison with other filters [to be] problematic in many ways,” and yet chose to
18 “avoid/downplay this as much as possible.” *Id.* Bard continued to sell the Recovery
19 filter even though it had information that the filter was fracturing at a rate higher than
20 other filters, was tilting in nearly a third of all patients, and was significantly less safe
21 than the SNF and competitor devices. *Id.* ¶¶ 47-48, 60-61. Despite this information,
22 Bard provided its employees with a Q&A “script” to follow stating that the Recovery
23 filter’s “overall complication rates are comparable to those reported in literature and in
24 the MAUDE database for other IVC filters.” *Id.* ¶ 54.

25 Plaintiff claims that instead of pulling the Recovery filter off the market and
26 starting over, Bard began marketing the next generation G2 filter without adequate
27 testing to determine whether underlying design problems had been fixed. Doc. 8167
28 at 21-22. By late 2005, Bard was aware that there was no significant change in

1 perforation rates between the Recovery and G2 filters and that G2 failure rates needed to
2 be investigated. Doc. 7950 ¶¶ 77-78. Bard also was aware that the G2 did not have
3 increased migration resistance over the Recovery and SNF, despite its representations to
4 the contrary. *Id.* ¶ 79. Bard later learned during a clinical study that the G2 tended to tilt
5 at an excessive rate and nearly half the patients had reported an adverse event. *Id.* ¶ 91.
6 With respect to fractures, Bard engineers did not conduct thorough testing because they
7 concluded that the data “would still fall outside the acceptable range” and would not
8 support the G2’s “design change as a viable option.” *Id.* ¶ 76.

9 This description of the evidence is made in the light most favorable to Plaintiff, as
10 required for a summary judgment ruling, and is disputed vigorously by Defendants. But
11 if believed by the jury at trial, this evidence is sufficient to support a finding that
12 Defendants “knew the G2 Filter was failing at a significantly higher rate than other IVC
13 filters but did nothing to correct the problem or to warn doctors or patients of the
14 increased risk.” *Cason*, 2015 WL 9913809, at *6. A jury reasonably could “conclude
15 that Bard acted with an entire want of care such that Bard was consciously indifferent to
16 the consequences of its actions.” *Cisson*, 2013 WL 5700513, at *14; *see Weilbrenner v.*
17 *Teva Pharms. USA, Inc.*, 696 F. Supp. 2d 1329, 1344 (M.D. Ga. 2010) (punitive damages
18 appropriate for jury consideration where drug manufacturer knew risks of adverse effects
19 in adolescents but did nothing to warn about the dangers); *Mack Trucks, Inc. v.*
20 *Conkle*, 436 S.E.2d 635, 640 (Ga. 1993) (punitive damages appropriate where truck
21 manufacturer failed to notify purchasers of frame problems); *Ford Motor Co. v.*
22 *Sasser*, 618 S.E.2d 47, 58 (Ga. Ct. App. 2005) (punitive damages warranted where
23 manufacturer was aware of danger from seat latching system but failed to warn
24 consumers).

25 Defendants contend that incidents involving the Recovery filter are irrelevant
26 because Plaintiff cannot show a “substantial similarity” between that device and the G2
27 filter. Doc. 8574 at 14-16. “To show substantial similarity, the plaintiff must come
28 forward with evidence that the other ‘incidents share a common design, common defect,

1 and common causation with the alleged design defect at issue.” *Chrysler Grp., LLC v.*
2 *Walden*, 792 S.E.2d 754, 740 (Ga. Ct. App. 2016) (quoting *Colp v. Ford Motor Co.*, 630
3 S.E.2d 886, 889 (Ga. 2006)). Plaintiff clearly has met this burden.

4 It is undisputed that the Recovery filter was the predicate device for the G2 and
5 that the two filters share a common design. Indeed, Defendants themselves acknowledge
6 that they filed a 510(k) notice in March 2005 “seeking clearance for a modified Recovery
7 Filter (subsequently known as the G2 Filter)[.]” Doc. 5396 at 8. The FDA cleared the
8 G2 as a permanent filter after finding it to be “substantially equivalent” to the Recovery
9 filter. *Id.* at 9. A device is “substantially equivalent” to a predicate device if it has the
10 same intended use and the same technological characteristics as the predicate device, or
11 any differences do not raise different safety issues. 21 U.S.C. § 360c(i)(1)(A).

12 What is more, Plaintiff has presented evidence that the two devices share common
13 design defects that have caused similar adverse events, namely, filter migration, fracture,
14 and perforation resulting in serious injury or death. Contrary to Defendants’ contention,
15 Plaintiff has shown a “substantial similarity” between the Recovery and G2 filters.⁷

16 Defendants contend that punitive damages are not warranted for any failure to
17 make design changes before June 2007 given the extensive design, testing, and regulatory
18 clearance processes that were required before any design changes could be implemented.
19 Doc. 8574 at 17. But the same cannot be said about providing warnings for Bard filters.
20 Indeed, Defendants acknowledge that the FDA previously has cleared labeling changes to
21 Bard IVC filters and in one instance found that no 510(k) clearance was even needed.
22 Doc. 5396 at 33.

23 Defendants claim that Georgia courts have denied punitive damages in
24 circumstances more egregious than those alleged here. Doc. 8574 at 18. The cases
25 Defendants cite, however, are distinguishable. *See Hernandez v. Crown Equip. Corp.*, 92
26 F. Supp. 3d 1325, 1357 (M.D. Ga. 2015) (forklift manufacturer was not consciously

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28 ⁷ Defendants’ reliance on *Ray v. Ford Motor Co.*, 514 S.E.2d 227 (Ga. Ct. App. 1999), is misplaced. The plaintiff in that case did not argue that the prior incidents were similar to her accident, and the evidence otherwise was unreliable. *Id.* at 231.

1 indifferent to the risk of leg or foot injuries in part because it “placed warnings on the
2 forklifts and in the operator’s manual relating to this danger”); *Moore v. Wright Tech.,*
3 *Inc.*, No. 1:14-cv-62, 2016 WL 1298975, at *6 (S.D. Ga. Mar. 31, 2016) (summary
4 judgment warranted where the plaintiff cited no legal authority and merely referenced the
5 defendant’s misconduct in general in support of punitive damages); *Stuckey v. N.*
6 *Propane Gas Co.*, 874 F.2d 1563, 1575 (11th Cir. 1989) (affirming denial of motion to
7 add punitive damages claim at trial and merely noting that the evidence did not justify an
8 award of punitive damages).

9 The Court will deny summary judgment on Plaintiff’s claim for punitive damages.

10 **IT IS ORDERED:**

11 1. Defendants’ motion for partial summary judgment (Doc. 7456) is **granted**
12 **in part** and **denied in part**. The motion is granted with respect to Plaintiff’s claims for
13 manufacturing defects (Counts I and V), failure to recall or retrofit (Count VI),
14 misrepresentation (Counts VIII and XII), negligence per se (Count IX), and breach of
15 warranty (Counts X and XI). The motion is denied with respect to Plaintiff’s claims for
16 failure to warn (Counts II and VII) and punitive damages. These claims, along with the
17 design defect claims (Counts III and IV), remain for trial.

18 2. A final pretrial conference is set for **February 23, 2018 at 2:00 p.m.** The
19 trial is set to begin on **March 13, 2018 at 9:00 a.m.** See Docs. 8104, 8858.

20 Dated this 22nd day of November, 2017.

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24 _____
25 David G. Campbell
26 United States District Judge
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1 **WO**

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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**

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9 IN RE: Bard IVC Filters Products Liability
10 Litigation,

No. MDL 15-02641-PHX-DGC

11
12 Doris Jones and Alfred Jones, Sr.,
13 a married couple,
14 Plaintiffs,

No. CV-16-00782-PHX-DGC

15 v.

ORDER

16 C. R. Bard, Inc., a New Jersey corporation;
17 and Bard Peripheral Vascular, Inc., an
18 Arizona corporation,
19 Defendants.

20 This multidistrict litigation proceeding (“MDL”) involves thousands of personal
21 injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular,
22 Inc. (collectively, “Bard”). Bard manufactures and markets medical devices, including
23 inferior vena cava (“IVC”) filters. The MDL Plaintiffs have received implants of Bard
24 IVC filters and claim that they are defective and have caused Plaintiffs to suffer serious
25 injury or death.

26 The case brought by Doris and Alfred Jones has been selected as one of several
27 bellwether cases and is set for trial in May 2018. Defendants have filed a motion for
28 partial summary judgment. Doc. 7351. The motion is fully briefed, and the parties agree

1 that oral argument is not necessary. For reasons set forth below, the Court will grant the
2 motion in part and deny it in part.¹

3 **I. Background.**

4 The IVC is a large vein that returns blood to the heart from the lower body. An
5 IVC filter is a small metal device implanted in the IVC to catch blood clots before they
6 reach the heart and lungs. This MDL involves seven different versions of Bard IVC
7 filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali. They are
8 spider-like devices that have multiple limbs fanning out from a cone-shaped head. The
9 limbs consist of legs with elastic hooks that attach to the IVC wall and curved arms that
10 serve to catch or break up blood clots. Each of these filters is a variation of its
11 predecessor.

12 The MDL Plaintiffs allege that Bard filters are more dangerous than other IVC
13 filters because they have higher risks of tilting, perforating the IVC, or fracturing
14 and migrating to vital organs. Plaintiffs further allege that Bard failed to warn physicians
15 and patients about these higher risks. Plaintiffs assert a host of state law claims and seek
16 both compensatory and punitive damages. Defendants dispute Plaintiffs' allegations,
17 contending that Bard filters are safe and effective, that their complication rates are low
18 and comparable to those of other IVC filters, and that the medical community is aware of
19 the risks associated with IVC filters.

20 **II. Plaintiffs Doris and Alfred Jones.**

21 In August 2010, before gastrointestinal surgery, Doris Jones was implanted with
22 an Eclipse filter due to recurrent deep vein thrombosis. Dr. Anthony Avino implanted the
23 filter without incident. In April 2015, Mrs. Jones went to the emergency room with
24 complaints of lightheadedness and arm pain. A chest scan revealed a fractured filter limb
25

26
27 ¹ The motion redacts certain information concerning Mrs. Jones's personal
28 medical history. Doc. 7531. Defendants have filed an unredacted version of that brief
under seal. Doc. 7354. The Court will cite to the redacted motion in addressing the
summary judgment arguments.

1 that had embolized in the right pulmonary artery. The filter was removed but the
2 fractured limb remains in place.

3 Mrs. Jones and her husband assert various claims under Georgia law, some of
4 which have been withdrawn. The following claims remain: failure to warn (Counts II
5 and VII), design defects (Counts III and IV), misrepresentation (Counts VIII and XII),
6 negligence per se (Count IX), fraudulent concealment (Count XIII), consumer fraud and
7 unfair trade practices (Count XIV), loss of consortium (Count XV), and punitive
8 damages. *See* Doc. 364 (master complaint); Doc. 1, CV-16-00782-PHX-DGC (short-
9 form complaint).²

10 Defendants seek summary judgment on the failure to warn, misrepresentation,
11 negligence per se, consumer fraud and unfair trade practices, and punitive damages
12 claims. Doc. 7351 at 3. Plaintiffs concede that summary judgment is proper on the
13 consumer fraud and unfair trade practices claim. Doc. 7943 at 2 n.1. The Court will
14 grant summary judgment on that claim and the misrepresentation and negligence per se
15 claims. The Court will deny summary judgment on the failure to warn and punitive
16 damages claims.³

17 **III. Summary Judgment Standard.**

18 A party seeking summary judgment “bears the initial responsibility of informing
19 the court of the basis for its motion, and identifying those portions of [the record] which
20 it believes demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v.*
21

22 ² The master complaint is the operative pleading for most of the cases in this
23 MDL. It was created for the sake of convenience and serves as a long-form complaint
24 giving notice, pursuant to Rule 8, of the allegations that Plaintiffs assert generally.
25 Plaintiff-specific allegations are contained in individual short-form complaints or certain
26 complaints served on Bard before the filing of the master complaint. *See* Doc. 249 at 6.
27 Plaintiffs also provide Bard with profile forms and fact sheets that describe their
28 individual conditions and claims. *See* Doc. 365.

29 ³ Defendants do not seek summary judgment on the claims for design defect
(Counts III and IV), fraudulent concealment (Count XIII), and loss of consortium (Count
30 XV). Plaintiffs withdrew the followings claims before Defendants moved for summary
31 judgment: manufacturing defect (Counts I and V), negligent failure to recall or retrofit
(Count VI), and breach of warranty (Counts X and XI). *See* Doc. 7351 at 2. Plaintiffs do
32 not assert claims for wrongful death or survival (Counts XVI and XVII).

1 *Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the moving party
2 shows that there is no genuine dispute as to any material fact and the movant is entitled to
3 judgment as a matter of law. Fed. R. Civ. P. 56(a). Only disputes over facts that might
4 affect the outcome of the suit will preclude the entry of summary judgment, and the
5 disputed evidence must be “such that a reasonable jury could return a verdict for the
6 nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The
7 evidence must be viewed in the light most favorable to the nonmoving party, *Matsushita*
8 *Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), and all justifiable
9 inferences are drawn in that party’s favor because “[c]redibility determinations,
10 the weighing of evidence, and the drawing of inferences from the facts are jury
11 functions,” *Anderson*, 477 U.S. at 255.

12 **IV. Failure to Warn (Counts II and VII).**

13 Georgia law applies in this case because the alleged injuries occurred in Georgia
14 and Plaintiffs lived there when their complaint was filed. Doc. 7351 at 5; Doc. 1 ¶¶ 4-6,
15 CV-16-00782-PHX-DGC. To establish a failure to warn claim under Georgia law,
16 “the plaintiff must show that the defendant had a duty to warn, the defendant breached
17 that duty and the breach was the proximate cause of the plaintiff’s injury.” *Wheat v.*
18 *Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999). “[A] manufacturer has a
19 duty to warn of nonobvious foreseeable dangers from the normal use of its product.”
20 *Thornton v. E.I. Du Pont de Nemours & Co.*, 22 F.3d 284, 289 (11th Cir. 1994). The duty
21 to warn arises “whenever the manufacturer knows or reasonably should know of the
22 danger arising from the use of its product.” *Chrysler Corp. v. Batten*, 450 S.E.2d 208,
23 211 (Ga. 1994). The duty may be breached in two ways: “(1) failing to adequately
24 communicate the warning to the ultimate user or (2) failing to provide an adequate
25 warning of the product’s potential risks.” *Thornton*, 22 F.3d at 289.

26 In cases involving medical devices, Georgia applies the “learned intermediary”
27 doctrine. Under this doctrine, the manufacturer has no “duty to warn the patient of the
28 dangers involved with the product, but instead has a duty to warn the patient’s doctor,

1 who acts as a learned intermediary between the patient and manufacturer.” *McCombs v.*
2 *Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003) (citing *Ellis v. C. R. Bard, Inc.*, 311
3 F.3d 1272, 1279-80 (11th Cir. 2002)). The manufacturer’s warnings to the physician,
4 however, “must be adequate or reasonable under the circumstances of the case.” *Id.*

5 In this case, Plaintiffs allege that Bard failed to adequately warn physicians about
6 the known defects and higher complication rates associated with Bard filters. Doc. 364
7 ¶¶ 174-78, 211-16. Plaintiffs claim that this failure constitutes a breach of Bard’s duty to
8 warn and proximately caused their injuries. *Id.* ¶¶ 177-81, 215-17. Plaintiffs assert strict
9 liability and negligence claims for the alleged failure to warn. *Id.* ¶¶ 171-81, 202-09; *see*
10 Doc. 1 at 3, CV-16-00782-PHX-DGC.

11 Defendants contend that proximate cause is lacking because Dr. Avino did not
12 read the Eclipse filter’s instructions for use (“IFU”) and had actual knowledge of the risk
13 of fracture. Doc. 7351 at 6-7. Defendants further contend that the warnings provided
14 with the Eclipse filter were adequate because they included the complication experienced
15 by Mrs. Jones. *Id.* at 8-11. The Court will address each argument.

16 **A. Causation.**

17 **1. Failure to Read the Eclipse IFU.**

18 Defendants rely on *Wilson Foods Corp. v. Turner*, 460 S.E.2d 532, 534 (Ga. Ct.
19 App. 1995), for the proposition that “failure to read product instructions . . . will prevent
20 a plaintiff from recovering on a claim grounded on failure to provide adequate warning of
21 the products’ potential risk.” Doc. 7351 at 6. Defendants contend that Dr. Avino did not
22 read the Eclipse IFU before implanting the device in Mrs. Jones, and Plaintiffs therefore
23 cannot show that any warning inadequacy proximately caused their injuries. *Id.*

24 But the duty to warn is breached not only by having a deficient warning, but also
25 by “failing to adequately communicate the warning to the ultimate user.” *Thornton*,
26 22 F.3d at 289. Indeed, *Wilson* makes clear that failure to read instructions “does not bar
27 recovery where the plaintiff is challenging the adequacy of the efforts of the
28 manufacturer or seller to communicate the dangers of the product to the buyer or user.”

1 460 S.E.2d at 534 (quoting *Thornton*, 22 F.3d at 290). Plaintiffs bring such a challenge
2 in this case.

3 Plaintiffs claim that the instructions contained in the IFU were inadequate, and
4 that Bard otherwise failed to communicate sufficient warnings to physicians.
5 Specifically, Plaintiffs allege that Bard breached its duty to warn by not “providing
6 instructions for safe use” or “communicating the information and dangers” about Bard
7 filters to physicians. Doc. 364 ¶¶ 181, 216. Plaintiffs note that medical device warnings
8 are provided in various ways, including “dear doctor” letters, product pamphlets, and
9 statements by the company sales representatives. Doc. 7943 at 14 (citing *Allen v.*
10 *Belinfante*, 458 S.E.2d 867, 869 (Ga. Ct. App. 1995) (assessing doctor’s awareness of
11 “dear doctor” letters and other sources of information about potential risks in determining
12 liability for failure to warn claim)); see *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 615 (2011)
13 (noting that manufacturers provide warnings through dear doctor letters).

14 Given Plaintiffs’ claim that Bard breached its duty to warn by failing to adequately
15 communicate warnings to physicians through means other than IFUs, the fact that
16 Dr. Avino may not have read the Eclipse IFU is not dispositive on causation. See *Jones*
17 *v. Amazing Prods., Inc.*, 231 F. Supp. 2d 1228, 1247 (N.D. Ga. 2002) (“A plaintiff’s
18 failure to read a warning will not . . . bar recovery as to the first prong of the test: namely,
19 where the plaintiff is challenging the *adequacy* of the defendant’s efforts to communicate
20 the dangers of the product to the user[.]” (citing *Wilson*, 460 S.E.2d at 534)); *In re Stand*
21 *’n Seal Prods. Liab. Litig.*, No. 1:07MD1804-TWT, 2009 WL 2145911, at *6 (N.D. Ga.
22 July 15, 2009) (denying summary judgment where the plaintiffs did not read the warning
23 label but claimed that the manufacturer’s efforts to communicate the dangers were
24 inadequate (citing *Wilson*)); *Mizell v. Pilgrim’s Pride Corp.*, No. CV 509-064, 2012 WL
25 130056600, at *5 (S.D. Ga. Mar. 14, 2012) (finding the failure to read a warning not
26 dispositive where the plaintiff challenged the manufacturer’s communication of the
27 warning (citing *Wilson*)); *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-
28 22DAB, 2007 WL 4117201, at *2 (M.D. Fla. Nov. 6, 2007) (denying summary judgment

1 where the plaintiffs alleged that the manufacture failed to communicate drug risks in dear
2 doctor letters and promotional materials used by sales representatives); *see also Flowers*
3 *v. Eli Lilly & Co.*, No. 3:14-cv-0094-LHR-VPC, 2015 WL 12622058, at *3 (D. Nev. July
4 10, 2015) (manufacturer met its duty to communicate potential risks by sending dear
5 doctor letters to physicians).⁴

6 **2. Knowledge of the Risk.**

7 Defendants note that the causal link is generally broken where the treating
8 physician has actual knowledge of the risk. Doc. 7351 at 7. Defendants contend that
9 proximate causation is lacking in this case because Dr. Avino was aware of IVC filter
10 complications – including fracture – before implanting the Eclipse filter in Mrs. Jones.
11 *Id.* Defendants further contend that Bard cannot be liable for failure to warn because IVC
12 filter complications are well known by the medical community. *Id.* at 9.

13 Plaintiffs concede that Bard warned Dr. Avino and other physicians about filter
14 complications generally, but contend that the warnings were inadequate because Bard did
15 not disclose that the risk of complications for the Eclipse filter was *higher* than those of
16 other IVC filters, including Bard’s own Simon Nitinol Filter (“SNF”). Doc. 7943 at 6-7,
17 10-11. Plaintiffs present evidence that the Eclipse and its predecessor devices, the
18 Recovery and G2 line of filters, involved substantially greater risks of fracture than other
19 IVC filters. Doc. 7943 at 4. Plaintiffs claim that Dr. Avino was not aware of the higher
20 risks, and that he would have wanted to know this information when deciding whether to
21 implant the Eclipse filter in Mrs. Jones. *Id.* Dr. Avino testified that his initial
22 understanding was that the fracture rates for Bard filters were very low, and he learned

23
24 ⁴ The parties dispute whether Dr. Avino actually read the Eclipse IFU. Dr. Avino
25 testified that he sometimes reads IFUs, but does not read them on every package where
26 the product is the same, and that he does not specifically recall if he read the Eclipse IFU.
27 Doc. 7357-3 at 5. Plaintiffs contend that Dr. Avino was aware of the warnings in the
28 Eclipse IFU because he read those very warnings for Bard’s G2 line of filters. Doc. 7943
at 13. The Court finds that there is a genuine factual dispute on this issue that is best
resolved by the jury. *See In re Stand ‘n Seal*, 2009 WL2145911, at *6 (finding triable
issue where the plaintiff could not remember whether he read the warnings and noting
that “[i]ssues of causation are for the jury to resolve and should not be determined by a
trial court as a matter of law except in plain and undisputed cases”).

1 only during the past several years that the rates were higher. Doc. 7974 at 42-43.
2 He further stated that the time period in which he treated Mrs. Jones “predates the peak of
3 his concern and the release of the warnings about the complications of filters.” *Id.*
4 at 33-34. He made clear that if Bard knew about higher complication rates associated
5 with its filters before Mrs. Jones’s surgery, he would have wanted to know that
6 information. *Id.* at 34, 45-46.

7 Construed in Plaintiffs’ favor, Dr. Avino’s testimony is sufficient evidence of
8 causation at the summary judgment stage. A jury reasonably could infer that he would
9 not have implanted the Eclipse filter in Mrs. Jones had he been warned about higher
10 fracture rates. *See In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. CV
11 2:10-cv-01224, 2013 WL 2431975, at *7 (S.D. W. Va. June 4, 2013) (denying summary
12 judgment where the doctor never explicitly stated that he would not have used Bard’s
13 product had he been provided additional warnings, but explained that the information
14 would have been “helpful” and “nice to have”); *Cason v. C. R. Bard, Inc.*, No. 1:12-CV-
15 1288-HMS, 2015 WL 9913809, at *6 (N.D. Ga. Feb. 9, 2015) (denying summary
16 judgment where the doctor stated that “he would have wanted to know if the G2 Filter
17 had a significantly higher risk of complications than other IVC filters”). Georgia law is
18 clear that summary judgment is warranted on the issue of causation only where the
19 physician testifies unequivocally that he would have made the same decision despite the
20 proposed warning. *See Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir.
21 2010) (doctor provided “explicit, uncontroverted testimony that, even when provided
22 with the most current research and FDA mandated warnings, he still would have
23 prescribed [the anti-depressant]”); *Porter v. Eli Lilly & Co.*, No. 1:06-CV-1297-JOF,
24 2008 WL 544739, at *13 (N.D. Ga. Feb. 25, 2008) (doctor “unequivocally testified that
25 even if he had read the warning that [plaintiff] asserts should have been given, he still
26 would have prescribed [the anti-depressant] to the decedent”). Defendants cite no such
27 testimony from Dr. Avino.⁵

28 ⁵ Defendants assert in their reply that Plaintiffs did not ask Dr. Avino during his

1 Defendants' reliance on *In re Wright Medical Technology Inc.*, 127 F. Supp. 3d
2 1306 (N.D. Ga. 2015), is misplaced. Doc. 7351 at 7. The undisputed evidence in that
3 case showed that the physician educated himself about product risks by reviewing the
4 medical literature, had never read package insert warnings for any device he implanted,
5 and did not have access to the insert prior to the plaintiff's surgery because it was in a
6 sterile package. 127 F. Supp. 3d at 1359-60. Moreover, the failure to warn claim was
7 governed by Utah law, not the law of Georgia. *See id.* at 1358.

8 Defendants' reliance on *Wheat* and *Ellis* fares no better. Doc. 7351 at 7-9. Each
9 treating physician in *Wheat* unequivocally testified that "he was aware of the risks
10 associated with spinal implant surgery, that such risks were well known in the medical
11 community, and that he would have taken the same course of action in spite of the
12 information [the plaintiffs] contend[ed] should have been provided." 46 F. Supp.
13 at 1363. *Ellis* held that a medical device manufacturer has no duty to warn anyone other
14 than the learned intermediary, and granted summary judgment because it was undisputed
15 that this duty had been met. 311 F.3d at 1281-83 ("[W]e conclude that Georgia's learned
16 intermediary rule controls this case, [and] that the defendants adequately warned the
17 doctors . . . of the damages of third-party [pain pump] activation[.]").⁶

18 **B. Adequacy of the Warnings.**

19 The Eclipse IFU included the following warnings:

20 Filter fracture is a known complication of vena cava filters. There have
21 been some reports of serious pulmonary and cardiac complications with

22
23 deposition whether a different warning would have mattered. Doc. 8391 at 10. But
24 apparently neither did Defendants. Absent unequivocal testimony in this regard,
25 summary judgment is not warranted. *See Watkins v. Eli Lilly & Co.*, No. 1:08-CV-1665,
2010 WL 11493785, at *9 (N.D. Ga. Mar. 31, 2010) (denying summary judgment where
the defendant failed to "nail[] this matter down" through deposition testimony).

26
27 ⁶ Defendants assert in their reply that Plaintiffs have presented no evidence that
28 the Eclipse filter fractured at a significant enough rate to render Bard's warnings about
fracture inadequate. Doc. 8391 at 9. Plaintiffs present evidence of significantly higher
fracture rates for the G2 filter, claim that the Eclipse is essentially the same as the G2,
and dispute whether electropolishing of the Eclipse was effective in reducing fracture
rates experienced by the G2. *Id.* at 4 n.3, 16. Given this evidence, the fracture rate for
Eclipse filters is an issue for the jury.

1 vena cava filters requiring the retrieval of the fragment utilizing
2 endovascular and/or surgical techniques.

3

4 [T]he above complications may be associated with serious adverse events
5 such as medical intervention and/or death. There have been reports of
6 complications including death, associated with the use of vena cava filters
7 in morbidly obese patients. The risk/benefit ratio of any of these
8 complications should be weighed against the inherent risk/benefit ratio for a
9 patient who is at risk of pulmonary embolism without intervention.

10 Doc. 7352-1. Defendants contend that these warnings were adequate as a matter of law
11 because they included a risk of fracture – the very complication experienced by Mrs.
12 Jones. Doc. 7351 at 8-9. Plaintiffs argue that the warnings were inadequate because they
13 did not include risk rates or disclose that the risks associated with the Eclipse filter were
14 higher than those for the SNF and other IVC filters. Doc. 7943 at 10. Anticipating this
15 argument, Defendants counter that Georgia law imposes no duty on a manufacturer to
16 provide comparative risk rates for its product and those of competitors. Doc. 7351
17 at 9-10.

18 The Court addressed this issue in ruling on Defendants’ summary judgment
19 motion in the Booker case. Agreeing with the decisions in *Cason* and *Cisson*, which
20 applied Georgia law, the Court found that whether Bard’s warnings were adequate is a
21 question of breach, not duty. Doc. 8874 at 6-7 (citing *Cason*, 2015 WL 9913809, at *4-5;
22 *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 5700513, at *7 (S.D. W. Va.
23 Oct. 18, 2003)). The Court reaches the same conclusion in this case.

24 The Court further finds that the alleged failure to warn about the rate of
25 complications raises a jury question over the adequacy of Bard’s warnings. “The general
26 rule in Georgia is that the adequacy of the warning is an issue for the jury [unless] . . . the
27 facts support only one conclusion, that is, the warning and its communication were
28 adequate.” *Thornton*, 22 F.3d at 289 (citations omitted). The evidence presented in this
case, when construed in the light most favorable to Plaintiffs, *see Matsushita*, 475 U.S.
at 587, supports a finding that Bard’s warnings for the Eclipse filter were not “adequate

1 or reasonable under the circumstances of the case.” *McCombs*, 587 S.E.2d at 595. The
2 “question that must be answered by the fact finder is whether the warning given was
3 sufficient or was inadequate because it did not ‘provide a complete disclosure of the
4 existence and extent of the risk involved.’” *Watkins v. Ford Motor Co.*, 190 F.3d 1213,
5 1220 (11th Cir. 1999) (quoting *Thornton*, 22 F.3d at 289). In short, whether the warnings
6 should have included comparative risk rates will be for the jury to decide. *See Cason*,
7 2015 WL 9913809, at *5 (“Given . . . that defendants did not warn Mrs. Cason’s doctor
8 about any increased risk associated with the G2 Filter, a reasonable fact finder could
9 conclude that the IFU did not contain an adequate warning[.]”); *Cisson*, 2013 WL
10 5700513, at *7 (failure to warn about “the rate or severity of potential injury creates a
11 jury question over the adequacy of warnings”); *Watkins*, 190 F.3d at 1219-20 (denying
12 summary judgment on failure to warn claim where Ford’s internal documents showed
13 that the Bronco II had a rollover fatality rate more than three times that of other SUVs
14 and the vehicle was rated last in government stability tests); *In re Mentor Corp. ObTape*
15 *Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1378 (M.D. Ga. 2010)
16 (finding a triable issue on adequacy of warning where the product had a greater
17 propensity to cause complications and was associated with more severe complications
18 than other products).

19 Defendants contend that Georgia law does not require a manufacturer to provide
20 comparative rates of complications for its products. Doc. 7351 at 9-10 (citing *Dixie Grp.,*
21 *Inc. v. Shaw Indus. Grp., Inc.*, 693 S.E.2d 888, 892 (Ga. Ct. App. 2010); *Hoffman v. AC*
22 *& S, Inc.*, 548 S.E.2d 379, 382 (Ga. Ct. App. 2001)). But as previously explained
23 (Doc. 8874 at 9), the cases cited by Defendants concern very different questions: whether
24 a manufacturer can be liable for injuries caused by modifications another party made to
25 its product, *Dixie Grp.*, 693 S.E.2d at 892, and whether a plaintiff must show that it was
26 the defendant’s asbestos product – as opposed to asbestos products generally – that
27 caused her mesothelioma, *Hoffman*, 548 S.E.2d at 382. “Nothing in these cases suggests
28 that a manufacturer’s warning is adequate even if it fails to warn that the product is

1 significantly more dangerous than other similar products on the market.” *Cason*, 2015
2 WL 9913809, at *5.

3 Defendants state in their reply that including warnings about comparative risk
4 rates “is almost certainly precluded by FDA regulations,” but they cite no specific
5 regulation in support of this assertion. Doc. 8391 at 6. Defendants’ reliance on cases
6 involving prescription drugs is misplaced because those cases concern a specific FDA
7 regulation not applicable to medical devices such as the Eclipse filter. *See* 21 C.F.R.
8 § 201.57(c)(7) (“The requirements in this section apply only to prescription drug
9 products[.]”).

10 Defendants further state that providing comparative warnings would be impossible
11 because the data for defining actual rates is inherently unreliable and ever-changing.
12 Doc. 8391 at 6-7. The question, however, is not whether Defendants were able to
13 provide completely accurate and up-to-date failure rate comparisons, but whether, prior
14 to Mrs. Jones’s surgery, “they had sufficient information such that they knew or should
15 have known that use of the [Eclipse filter] involved a significantly increased risk of
16 [fracture] as compared to other IVC filters.” *Cason*, 2015 WL 9913809, at *6. As
17 explained above, a jury reasonably could conclude that Defendants had such information
18 and therefore had a duty to warn Dr. Avino of the increased risk.

19 Finally, Defendants contend that summary judgment is warranted because
20 Plaintiffs have identified no alternative warning. Doc. 8391 at 8-9 (citing *Nolley v.*
21 *Greenlee Textron, Inc.*, No. 1:06-CV-228-MHS, 2007 WL 5369405, at *6 (N.D. Ga.
22 Dec. 6, 2007)). To the contrary, Plaintiffs make clear Bard should have disclosed to
23 implanting physicians such as Dr. Avino that Bard filters (including the Eclipse)
24 fractured at rates significantly higher than the SNF and competitor filters. Doc. 7943
25 at 2, 7, 10. The jurors in this case, unlike in *Nolley*, will be presented with proposed
26 warnings and will have a means by which to determine whether the actual warnings were
27 adequate.

28 In summary, there are triable issues as to whether Bard’s warnings in this case

1 were adequate and whether Bard sufficiently communicated the warnings to Dr. Avino.
2 The Court will deny summary judgment on Plaintiffs' failure to warn claims (Counts II
3 and VII).

4 **V. Misrepresentation (Counts VIII and XII).**

5 Defendants contend that the misrepresentation claims fail for the same reasons the
6 failure to warn claims fail, namely, that Bard provided adequate warnings and the alleged
7 failure to warn could not be the proximate cause of Plaintiffs' injuries. Doc. 7351 at 6.
8 For reasons explained above, the failure to warn claims survive summary judgment.

9 Defendants also note, however, that Georgia does not recognize a claim for
10 misrepresentation apart from a failure to warn claim in products liability cases. *Id.* at 6
11 n.2.⁷ Defendants rely on two district court cases: *Brazil v. Janssen Research &*
12 *Development, LLC*, 249 F. Supp. 3d 1321, 1340 (N.D. Ga. 2016), and *Swicegood v.*
13 *Pliva, Inc.*, 543 F. Supp. 2d 1351, 1357 (N.D. Ga. 2008). In *Swicegood*, the plaintiff
14 brought a products liability action after she allegedly suffered an adverse reaction to a
15 generic prescription drug. 543 F. Supp. 2d at 1353. The plaintiff alleged, among other
16 things, that the defendants knew that long-term use of the drug posed a greater risk of
17 causing the adverse reaction than they disclosed to the FDA or the public. *Id.* The
18 plaintiff asserted several claims under Georgia law, including strict products liability,
19 failure to warn, and misrepresentation. *Id.* at 1353-57. The court concluded that
20 "misrepresentation claims against a manufacturer properly collapse into the failure to
21 warn claims." *Id.* at 1357. Absent clear Georgia precedent, the court declined
22 "to recognize the viability of misrepresentation claims distinct from products liability or
23 failure to warn claims." *Id.*

24 The court in *Brazil* reached a similar conclusion. The court dismissed the plaintiff's
25

26 ⁷ Defendants made the same argument in seeking summary judgment on the
27 misrepresentation claims in the Booker case (Doc. 7460 at 7-8 n.3), but withdrew this
28 position at oral argument in Booker for reasons they did not explain (*see* Doc. 8874 at 14
n.5).

1 misrepresentation claim, noting that *Swicegood* had “determined that there [are] no
2 misrepresentation claims for products liability distinct from failure to warn claims.” 249 F.
3 Supp. 3d at 1340; *see Gaddy v. Terex Corp.*, 1:14-cv-1928-WSD, 2017 WL 3476318,
4 at *5 (N.D. Ga. May 5, 2017) (same).

5 The Court finds these rulings by Georgia-based federal judges, applying Georgia
6 law, to be persuasive. *See also In re Darvocet, Darvon & Propoxyphene Prods. Liab.*
7 *Litig.*, 856 F. Supp. 2d 904, 910 (E.D. Ky. 2012) (citing *Swicegood* and noting that
8 “courts in many states have expressly rejected the argument that misrepresentation claims
9 are distinct from product liability or failure-to-warn claims” (citations omitted)). The
10 Court will grant summary judgment on the misrepresentation claims (Counts VII and
11 XII).

12 Plaintiffs note that *Potts v. UAP-GA AG CHEM, Inc.*, 567 S.E.2d 316, 318 (Ga.
13 Ct. App. 2002), contemplated that a misrepresentation claim could be distinct from a
14 failure to warn claim in a products liability suit. But the misrepresentation claim in *Potts*
15 was truly distinct. It was asserted against the decedent’s former employer for allegedly
16 misrepresenting to a physician that the decedent was not exposed to the chemicals at
17 issue. 567 S.E.2d at 319-20. Unlike the misrepresentation claims asserted in this case,
18 the claim in *Potts* was distinct from the strict liability and failure to warn claims asserted
19 against the manufacturer. *Id.* (“Here the misrepresentation was to LeBlanc’s physician,
20 on whom LeBlanc was relying for treatment. Through the misrepresentation, [the
21 employer] induced the physician to discount the possibility of chemical poisoning and to
22 change LeBlanc’s treatment, on which treatment LeBlanc was relying for his physical
23 recovery.”).⁸

24 **VI. Negligence Per Se (Count IX).**

25 “In Georgia, ‘the violation of a statute, ordinance or mandatory regulation that
26

27 ⁸ Defendants assert in their reply that even if Georgia recognized separate products
28 liability misrepresentation claims, Plaintiffs offer no evidence of the required elements,
such as scienter and justifiable reliance. Doc. 8391 at 12. The Court will not grant
summary judgment based on an argument raised for the first time in a reply brief.
See Zamani v. Carnes, 491 F.3d 990, 997 (9th Cir. 2007).

1 imposes a legal duty for the protection of others constitutes negligence per se.” *Ashton*
2 *Park Trace Apartments, LLC v. W. Oilfields Supply Co.*, No. 14-CV-4056-MHC, 2015
3 WL 12469074, at *6 (N.D. Ga. July 16, 2015) (citation omitted). This theory of liability
4 is codified in a Georgia statute: “When the law requires a person to perform an act for
5 the benefit of another or to refrain from doing an act which may injure another, although
6 no cause of action is given in express terms, the injured party may recover for the breach
7 of such legal duty if he suffers damage thereby.” Ga. Code Ann. § 51-1-6.

8 Plaintiffs allege that Defendants are liable for negligence per se because they
9 violated various provisions of the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C.
10 § 301 *et seq.*, and related regulations, by misbranding Bard filters, making false and
11 misleading statements about the filters, failing to notify the FDA when the filters were no
12 longer safe and effective, failing to recall the devices, and not maintaining accurate
13 adverse event reports. Doc. 364 ¶ 231.⁹ This claim is impliedly preempted under
14 21 U.S.C. § 337(a), Defendants argue, because no private right of action exists under the
15 FDCA and all proceedings to enforce or restrain violations of the statute must be brought
16 by the FDA. Doc. 7351 at 11-12. The Court agrees with Defendants.¹⁰

17 “The FDCA leaves no doubt that it is the Federal Government rather than private
18 litigants who are authorized to file suit for noncompliance with the medical device
19 provisions.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 n.4 (2001).
20 Indeed, § 337(a) expressly provides that “all . . . proceedings for the enforcement, or to
21 restrain violations, of [the FDCA] shall be by and in the name of the United States.”
22 Thus, “a private litigant cannot bring a state-law claim against a defendant when the
23 state-law claim is in substance (even if not in form) a claim for violating the FDCA –
24 that is, when the state claim would not exist if the FDCA did not exist.” *Leonard v.*

25
26
27 ⁹ Specifically, Plaintiffs allege violations of 21 U.S.C. §§ 321, 331, 352, and
21 C.F.R. §§ 1.21, 801, 803, 807, 820. Doc. 364 ¶ 231(a)-(j).

28 ¹⁰ The Court reached the same conclusion in the Booker case. *See* Doc. 8874
at 14-18.

1 *Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *7 (N.D. Ga. Aug. 19,
2 2011) (citation omitted).

3 Plaintiffs assert no violation of a Georgia ordinance, regulation, or statute in
4 support of their negligence per se claim. Thus, “as in *Buckman*, [Plaintiffs’] negligence
5 per se claim (or, more appropriately characterized, [their] negligence claim based solely
6 on violations of the FDA-Imposed Requirements or other FDA regulations) is impliedly
7 preempted by the FDCA.” *Grant v. Corin Grp. PLC*, No. 3:15-CV-169-CAB-BLM,
8 2016 WL 4447523, at *4 (S.D. Cal. Jan. 15, 2016); *see Buckman*, 531 U.S. at 353 (state
9 law claim that a defendant violated the FDCA by making false statements to the FDA
10 impliedly preempted by § 337(a) because the claim “exist[ed] solely by virtue” of the
11 FDCA); *Leonard*, 2011 WL 3652311, at *8 (finding negligence per se claim preempted
12 by § 337(a) where it “would not exist prior to the enactment of the FDCA misbranding
13 and adulteration laws because the claim only alleges violation of that law”).

14 Plaintiffs assert that *Leonard* is inapposite because, unlike Bard IVC filters, the
15 medical device at issue in *Leonard* had been approved by the FDA through the rigorous
16 premarket approval process. Doc. 7943 at 18. But this was not the basis for *Leonard*’s
17 implied preemption finding. *Leonard* found implied preemption because “all
18 proceedings to enforce or restrain violations of the FDCA ‘shall be by and in the name of
19 the United States.’” 2011 WL 3652311, at *7 (quoting § 337(a)). Moreover, preemption
20 under § 337(a) is not limited to devices approved through the premarket approval
21 process. The device at issue in *Buckman* – like the Eclipse filter in this case – was
22 cleared for market under 510(k) review. 531 U.S. at 346-47.

23 Plaintiffs note that Georgia common law and § 51-1-6 recognize that laws which
24 do not create a private right of action may nonetheless support a claim for damages.
25 Doc. 7943 at 18-19 (citing *Amick v. BM & KM, Inc.*, 275 F. Supp. 2d 1378, 1282-83
26 (N.D. Ga. 2003) (finding that “the defendants breached the legal duties imposed by
27 [Georgia code] sections 30-4-2 and 43-21-3 when they prohibited Amick and his service
28 dog from staying at their hotel”). While it is true that courts generally have allowed a

1 negligence per se claim based on violation of a statute that does not expressly provide for
2 a private right of action, “the plain language of § 337(a) and the *Buckman* decision
3 indicate that, where the FDCA is concerned, such claim fails.” *Dunbar v. Medtronic,*
4 *Inc.*, No. CV 14-01529-RGK AJWX, 2014 WL 3056026, at *6 (C.D. Cal. June 25, 2014).

5 The Court will grant summary judgment on Plaintiffs’ negligence per se claim
6 because allowing the claim to go forward would authorize an impermissible action to
7 enforce provisions of the FDCA and its implementing regulations. *See Leonard*, 2011
8 WL 3652311, at *7-8; *Franklin v. Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010
9 WL 2543579, at *8 (D. Colo. May 12, 2010) (negligence per se claim preempted where it
10 was based on allegations that the defendant violated the FDCA by selling a misbranded
11 and adulterated product); *Connelly v. St. Jude Med., Inc.*, No. 5:17-cv-02005-EJD, 2017
12 WL 3619612, at *5 (N.D. Cal. Aug. 23, 2017) (negligence per se claim preempted where
13 it was “based entirely on violations of the FDCA and its implementing regulations”);
14 *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (finding fraud on the FDA claim
15 preempted where the plaintiff was not suing under state law for conduct that happens to
16 violate the FDCA, but instead is suing solely “because the conduct violates the FDCA.”).

17 **VII. Punitive Damages.**

18 Under Georgia law, punitive damages may be awarded only where the defendant’s
19 actions “showed willful misconduct, malice, fraud, wantonness, oppression, or that entire
20 want of care which would raise the presumption of conscious indifference to
21 consequences.” Ga. Code Ann. § 51-12-5.1(b). Defendants contend that punitive
22 damages are not warranted because there is no evidence Bard acted with the requisite
23 state of mind, and Bard otherwise complied with all applicable FDA regulations in
24 bringing its filters to market. Doc. 7351 at 12-13. “Compliance with federal regulations,
25 however, is not sufficient to automatically preclude an award of punitive damages.”
26 *Cason*, 2015 WL 9913809, at *6. This is particularly true where, as in this case, the
27 device at issue was cleared by the FDA under 510(k) review which focuses primarily on
28 equivalence with other products, not safety. *Cisson*, 2013 WL 5700513, at *12.

1 Plaintiffs claim that Bard’s actions show a conscious indifference to the dangerous
2 consequences posed by the Eclipse and its predecessor filters. Doc. 7943 at 19-23.
3 Plaintiffs argue that a jury reasonably could award punitive damages because there is
4 evidence that Bard knew that its retrievable filters were less safe than the SNF and were
5 failing at higher rates than competitor devices, and yet never identified the root cause of
6 the failures, provided adequate warnings, or recalled or suspended sales of Bard filters.
7 *Id.* at 20-23. The Court previously found that Plaintiffs have presented evidence that, if
8 believed by a jury, would be sufficient to support a finding that Bard knew the G2 filter
9 was failing at significantly higher rates than other IVC filters, but did nothing to correct
10 the problem or to warn doctors of the increased risk. Doc. 8874 at 20. Plaintiffs claim
11 that the Eclipse is just a rebranded G2 or G2X filter, citing an internal Bard document
12 explaining that the filter’s name was changed to “break with the baggage associated with
13 the previous versions despite the fact that the new iteration was the same as G2X in every
14 way but one.” Doc. 7943 at 22 (citing Doc. 7950 ¶ 102, Ex. 99).¹¹

15 Defendants counter that the design change made to the Eclipse – electropolishing
16 – was intended to improve fracture resistance and precludes a finding that Bard did
17 “nothing” to address the issue of fracture. Doc. 8391 at 15-16. But Plaintiffs claim that
18 Bard consciously chose not employ other known safety features in the Eclipse such as
19 penetration limiters and caudal anchors to reduce the risk of perforation, tilt, and
20 migration. Doc. 7943 at 22. Plaintiffs’ expert on the design of Bard filters opines that
21 filter failure modes can work synergistically, and that fractures are more likely to occur
22 when a filter tilts, migrates, or perforates the IVC wall. Docs. 7807-1 at 21, 7319-1
23 at 37-38. Plaintiffs contend that the Eclipse suffered from the same design defects and
24 caused the same type of injuries as its predecessors, and that rather than recalling the
25 product from the market, making substantive design changes to improve patient safety, or
26 warning physicians about the dangers, Bard simply renamed the device and continued

27
28 ¹¹ The only modification to the G2X from the G2 was the addition of a snare hook
to improve retrievability. The filters otherwise are the same.

1 selling it. Doc. 7943 at 22. Plaintiffs claim that the Eclipse was used as a stop-gap
2 device so that Bard could maintain market share and profits while it engaged in a
3 complete redesign of the filter. *Id.* at 22, 24-25.

4 Defendants vigorously dispute this view of the evidence, and claim that Bard
5 could not have brought its subsequent generation filters to market by the time Mrs. Jones
6 received an Eclipse filter. But if a jury were to believe Plaintiffs' version of events, it
7 reasonably could "conclude that Bard acted with an entire want of care such that Bard
8 was consciously indifferent to the consequences of its actions." *Cisson*, 2013 WL
9 5700513, at *14.

10 Defendants contend that incidents involving the Recovery and G2 line of filters
11 are irrelevant because Plaintiffs cannot show a "substantial similarity" between those
12 devices and the Eclipse. Doc. 8574 at 14-16. "To show substantial similarity, the
13 plaintiff must come forward with evidence that the other 'incidents share a common
14 design, common defect, and common causation with the alleged design defect at issue.'"
15 *Chrysler Grp., LLC v. Walden*, 792 S.E.2d 754, 740 (Ga. Ct. App. 2016) (quoting *Colp v.*
16 *Ford Motor Co.*, 630 S.E.2d 886, 889 (Ga. 2006)). Plaintiffs have met this burden.

17 It is undisputed that the Recovery filter was the predicate device for the G2, and
18 Plaintiffs have presented evidence that the two devices share common design defects that
19 have caused similar complications. *See* Docs. 8874 at 21, 10258 at 2-3. Plaintiffs also
20 have presented evidence that the Eclipse is the same as the G2 line of filters with only
21 one modification (electropolishing). Doc. 7950 ¶¶ 96, 101-102. Although the Eclipse
22 may not be identical to the Recovery and G2, Plaintiffs have shown a "substantial
23 similarity" between the filters.

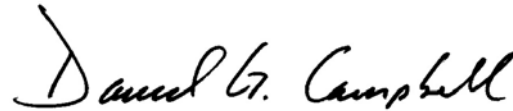
24 **IT IS ORDERED:**

25 1. The following claims are **dismissed** based on Plaintiffs' withdrawal of the
26 claims before Defendants moved for summary judgment: manufacturing defect (Counts I
27 and V), negligent failure to recall or retrofit (Count VI), and breach of warranty (Counts
28 X and XI).

1 2. Defendants' motion for partial summary judgment (Doc. 7351) is **granted**
2 **in part and denied in part**. The motion is granted with respect to Plaintiffs' claims for
3 misrepresentation (Counts VIII and XII), negligence per se (Count IX), and consumer
4 fraud and unfair trade practices (Count XIV). The motion is denied with respect to the
5 claims for failure to warn (Counts II and VII) and punitive damages. These claims, along
6 with the claims for design defect (Counts III and IV), fraudulent concealment (Count
7 XIII), and loss of consortium (Count XV), remain for trial.

8 3. A final pretrial conference is set for **May 4, 2018 at 10:00 a.m.**
9 Doc. 10324. The trial is set to begin on **May 15, 2018 at 9:00 a.m.** Doc. 8144.

10 Dated this 12th day of March, 2018.

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14 David G. Campbell
15 United States District Judge
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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products Liability
Litigation,

No. MDL 15-02641-PHX DGC

Doris Jones and Alfred Jones, Sr.,
Plaintiffs,

No. CV-16-00782-PHX-DGC

v.

C. R. Bard, Inc., a New Jersey corporation;
and Bard Peripheral Vascular, Inc., an
Arizona corporation,
Defendants.

ORDER

The Jones trial is set to begin on **May 15, 2018 at 9:00 a.m.** A final pretrial conference will be held on **May 4, 2018 at 10:00 a.m.** In preparation for trial, the Court enters the following orders:

1. The attorneys who will be responsible for the trial of the case shall attend the final pretrial conference.

2. The parties jointly shall prepare a proposed final pretrial order and shall lodge it with the Court no later than **4:00 p.m.** on **April 27, 2018.** Preparation and lodging of the proposed final pretrial order in accordance with the requirements of this order shall be deemed to satisfy the disclosure requirements of Rule 26(a)(3) of the Federal Rules of Civil Procedure. The parties shall submit a copy of the proposed final

1 pretrial order to the Court in Word format to Nancy.Outley@azd.uscourts.gov.

2 3. The proposed final pretrial order shall include the information prescribed in
3 the Joint Proposed Final Pretrial Order form found at www.azd.uscourts.gov under:
4 (1) Judges' Information, (2) Orders, Forms and Procedures, and (3) David G. Campbell.
5 Information shall not be set forth in the form of a question, but shall be presented in
6 concise narrative statements. With respect to jury instructions and the verdict form, the
7 Court intends to use the preliminary and final jury instructions and the verdict form from
8 the Booker trial. The parties need not follow the jury instruction form found at
9 www.azd.uscourts.gov, but instead should simply submit their stipulated and proposed
10 changes to the Booker instructions and verdict form. With respect to voir dire, the Court
11 intends to ask the voir dire questions from the Booker trial. The parties should submit
12 only stipulated and proposed changes to the Booker voir dire questions.

13 4. The Court will not allow the parties to offer any exhibit, witness, or other
14 evidence that was not disclosed in accordance with the provisions of this order and the
15 Federal Rules of Civil Procedure and listed in the proposed final pretrial order, except to
16 prevent manifest injustice. Fed. R. Civ. P. 16(e). Objections to witnesses and documents
17 should also be listed.

18 5. Plaintiffs shall have the burden of initiating communications concerning the
19 proposed final pretrial order.

20 6. The parties shall (a) number and mark exhibits in accordance with the
21 Exhibit Marking Instructions at www.azd.uscourts.gov under Judges and Courtrooms and
22 Orders, Forms and Procedures (such numbers shall correspond to exhibits numbers listed
23 in the proposed final pretrial order); (b) meet in person and exchange marked copies of
24 all exhibits to be used at trial no later than **14 days** before the submission deadline for the
25 proposed final pretrial order; and (c) eliminate any duplicate exhibits while meeting to
26 exchange exhibits.

27 7. The parties shall file and serve all motions in limine no later than
28 **April 18, 2018**. Responses to motions in limine shall be filed on or before

1 **April 25, 2018.** Each motion in limine shall state with precision the evidence that is the
2 subject of the motion. The motions and responses must be concise and shall not exceed
3 three (3) pages in length. No replies shall be filed. Counsel shall be prepared to argue
4 the merits of such motions at the final pretrial conference.

5 8. The Court will hold a hearing on **April 13, 2018 at 10:00 a.m.**, to discuss
6 issues decided in connection with the Booker trial that a party believes should be
7 reconsidered for the Jones trial. The parties shall file 5-page memoranda identifying the
8 issues they wish to be reconsidered, and summarizing their reasons, by **5:00 p.m.**
9 Phoenix time on **April 10, 2018**. The memoranda should identify the docket numbers for
10 briefs and orders that previously addressed the issues.

11 9. The parties shall provide deposition designations for the Court's ruling by
12 **4:00 p.m. on April 20, 2018.**

13 10. In order to facilitate the creation of an accurate record, the parties shall file
14 a "Notice to Court Reporter" **on or before May 8, 2018** containing the following
15 information that may be used at trial:

- 16 (a) Proper names, including those of witnesses.
- 17 (b) Acronyms.
- 18 (c) Geographic locations.
- 19 (d) Technical (including medical) terms, names or jargon.
- 20 (e) Case names and citations.
- 21 (f) Pronunciation of unusual or difficult words or names.


22 11. Trial will be held on **May 15-18, 22-25, 29-31, and June 1, 2018**. On the
23 basis of time used during the Booker trial, the fact that the Court believes the parties
24 could have been more efficient, and the fact that Plaintiffs have the burden of proof, the
25 Court will allocate **28 hours** to Plaintiffs and **27 hours** to Defendants.

26 12. The parties have stipulated to bifurcating the Jones trial into two phases
27 following the procedures set out in Georgia's statute on punitive damages, O.C.G.A.
28 § 51-12-5.1(d)(2). The first phase will determine liability, compensatory damages, and

1 whether punitive damages should be awarded. If necessary, the second phase will
2 determine the amount of punitive damages. *See* Doc. 10048. The parties are reminded
3 that if a second phase is needed, any time devoted to this punitive damages portion of the
4 trial will be counted against the hours allotted to each side in paragraph 11 above.

5 13. Jury selection and use of jury questionnaires will be as outlined in the order
6 at Doc. 10324.

7 Dated this 30th day of March, 2018.

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12 David G. Campbell
13 United States District Judge
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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products Liability
Litigation,

No. MDL 15-02641-PHX DGC

Debra Mulkey,

Plaintiff,

No. CV-16-00853-PHX-DGC

v.

C. R. Bard, Inc., a New Jersey corporation;
and Bard Peripheral Vascular, Inc., an
Arizona corporation,

ORDER

Defendants.

The Mulkey trial is set to begin on **September 18, 2018 at 9:00 a.m.** A final pretrial conference will be held on **August 30, 2018 at 10:00 a.m.** In preparation for trial, the Court enters the following orders:

1. The attorneys who will be responsible for the trial of the case shall attend the final pretrial conference.

2. The parties jointly shall prepare a proposed final pretrial order and shall lodge it with the Court no later than **4:00 p.m. on August 17, 2018.** Preparation and lodging of the proposed final pretrial order in accordance with the requirements of this order shall be deemed to satisfy the disclosure requirements of Rule 26(a)(3) of the Federal Rules of Civil Procedure. The parties shall submit a copy of the proposed final pretrial order to the Court in Word format to Nancy_Outley@azd.uscourts.gov.

1 3. The proposed final pretrial order shall include the information prescribed in
2 the Joint Proposed Final Pretrial Order form found at www.azd.uscourts.gov under:
3 (1) Judges' Information, (2) Orders, Forms and Procedures, and (3) David G. Campbell.
4 Information shall not be set forth in the form of a question, but shall be presented in
5 concise narrative statements. With respect to jury instructions and the verdict form, the
6 Court intends to use the preliminary and final jury instructions and the verdict form from
7 the Booker trial. The parties need not follow the jury instruction form found at
8 www.azd.uscourts.gov, but instead should simply submit their stipulated and proposed
9 changes to the Booker instructions and verdict form. With respect to voir dire, the Court
10 intends to ask the voir dire questions from the Booker trial. The parties should submit
11 only stipulated and proposed changes to the Booker voir dire questions.

12 4. The Court will not allow the parties to offer any exhibit, witness, or other
13 evidence that was not disclosed in accordance with the provisions of this order and the
14 Federal Rules of Civil Procedure and listed in the proposed final pretrial order, except to
15 prevent manifest injustice. Fed. R. Civ. P. 16(e). Objections to witnesses and documents
16 should also be listed.

17 5. Plaintiffs shall have the burden of initiating communications concerning the
18 proposed final pretrial order.

19 6. The parties shall (a) number and mark exhibits in accordance with the
20 Exhibit Marking Instructions at www.azd.uscourts.gov under Judges and Courtrooms and
21 Orders, Forms and Procedures (such numbers shall correspond to exhibits numbers listed
22 in the proposed final pretrial order); (b) meet in person and exchange marked copies of
23 all exhibits to be used at trial no later than **14 days** before the submission deadline for the
24 proposed final pretrial order; and (c) eliminate any duplicate exhibits while meeting to
25 exchange exhibits.

26 7. The parties shall file and serve all motions in limine no later than
27 **July 27, 2018**. Responses to motions in limine shall be filed on or before
28 **August 10, 2018**. Each motion in limine shall state with precision the evidence that is

1 the subject of the motion. The motions and responses must be concise and shall not
2 exceed three (3) pages in length. No replies shall be filed. Counsel shall be prepared to
3 argue the merits of such motions at the final pretrial conference.

4 8. The parties shall provide deposition designations for the Court's ruling by
5 **4:00 p.m. on August 15, 2018.**

6 10. In order to facilitate the creation of an accurate record, the parties shall file
7 a "Notice to Court Reporter" **on or before August 17, 2018** containing the following
8 information that may be used at trial:

- 9 (a) Proper names, including those of witnesses.
10 (b) Acronyms.
11 (c) Geographic locations.
12 (d) Technical (including medical) terms, names or jargon.
13 (e) Case names and citations.
14 (f) Pronunciation of unusual or difficult words or names.

15 11. Trial will be held on **September 18-21, 24-28, and October 1-5, 2018.**
16 The Court will allocate **33 hours** to Plaintiffs and **30 hours** to Defendants.

17 12. Jury selection and use of jury questionnaires will be as outlined in the order
18 at Doc. 11320.

19 Dated this 1st day of June, 2018.

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23 David G. Campbell
24 United States District Judge
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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**

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9 IN RE: Bard IVC Filters Products Liability
10 Litigation,

No. MDL 15-02641-PHX DGC

11 **CASE MANAGEMENT ORDER**
12 **NO. 34**

13
14 Following the close of the second bellwether trial, the Court conferred with the
15 parties regarding scheduling matters. The parties agreed on the Mulkey case as the next
16 bellwether trial for September 2018. The Court directed the parties to file memoranda
17 addressing other bellwether trials and cases in this MDL. Doc. 11320. Having reviewed
18 the memoranda, the Court enters the following order:

19 **I. Next Three Bellwether Trials: Kruse, Hyde, and Mulkey.**

20 During a recent telephonic conference, counsel for Ms. Mulkey expressed concern
21 about her availability for trial in September due to certain health issues. Doc. 11549.
22 Counsel thereafter provided an update on her condition which leaves her availability for
23 trial uncertain. Doc. 11639. Defendants have no objection to a different case for the next
24 bellwether, and propose Kruse in lieu of Mulkey. Doc. 11640. Plaintiffs propose Hyde
25 as the next bellwether. Doc. 11553.

26 Having considered the parties' positions, the Court concludes that the order of the
27 next three bellwether trials should be as follows: Kruse, Hyde, and Mulkey. Trial in the
28 Kruse bellwether will begin in **September 2018** as set forth below. Trial in the Hyde

1 bellwether will be held on **November 5-9, 12-16, and 19-20**. Trial in the Mulkey
2 bellwether will be held in **February 2019**. The Court will set the specific trial dates by
3 separate order.

4 **II. Kruse Trial.**

5 The dates and deadlines set forth in Case Management Order No. 33 for the
6 Mulkey trial will apply to the Kruse bellwether as follows (see Doc. 11320 for further
7 details):

8 **A. Jury Questionnaire and Jury Selection for Kruse Trial.**

9 1. By **July 5, 2018**, the parties shall provide the Court with proposed
10 changes to the questionnaire used in the Jones bellwether trial. The Court will consider
11 these proposals in finalizing the questionnaire for the Kruse trial.

12 2. The Clerk shall mail the questionnaire to 200 jurors no later than
13 **July 13, 2018**. The questionnaire will instruct the prospective jurors to return it to the
14 Court no later than **August 10, 2018**.

15 3. A thumb drive will be prepared for counsel (one for each side)
16 containing copies of the questionnaires and will be available for pickup at the jury office
17 on **August 17, 2018**. The thumb drive and any paper copies made by counsel must be
18 returned to the Court by counsel on the day of jury selection.

19 4. On **August 24, 2018**, the Court will provide the parties with a list of
20 prospective jurors the Court proposes to excuse for hardship on the basis of their
21 responses to the first question in the questionnaire.

22 5. The Court will hold a final pretrial conference in the Kruse case on
23 **August 30, 2018 at 10:00 a.m.** and will address with the parties juror excusals for
24 hardship and challenges for cause. *See* Doc. 11320 at 2, ¶ 2(e).

25 6. On **September 18, 2018, at 9:00 a.m.**, 50 prospective jurors will be
26 called to Court to appear for voir dire. Following voir dire, the Court will hear and rule
27 on challenges for cause. The Court will seat 9 jurors. Each side will have 3 pre-emptory
28 strikes. *See* Doc. 11320 at 2, ¶ 2(f).

1 **B. Kruse Motion for Summary Judgment.**

2 The Court will rule on the Kruse summary judgment motion as soon as possible.

3 **C. Motions in Limine.**

4 Motions in limine, limited to three pages each, shall be filed by **July 27, 2018**.
5 Responses to motions in limine, limited to three pages each, shall be filed by
6 **August 10, 2018**. No replies shall be filed.

7 Defendants may re-urge their motion in limine regarding Recovery death evidence
8 (Doc. 9862) pursuant to the schedule set forth above. Memoranda on this issue may be
9 up to 5 pages long. The parties shall not repeat arguments previously made. The issue
10 was fully briefed for the Booker trial, and the Court has addressed Recovery death
11 evidence in several orders. Docs. 10258, 10819, 10920, 11041.¹

12 **D. Deposition Designations.**

13 The parties shall provide deposition designations by **August 15, 2018**.

14 **E. Proposed Final Pretrial Order.**

15 The proposed final pretrial order for the Kruse bellwether shall be submitted by
16 **August 17, 2018**. The Court will enter a separate order governing the materials that
17 should be submitted with the proposed final pretrial order.

18 **F. Trial days.**

19 Trial in the Kruse bellwether will be held on **September 18-21** and **24-28**, and
20 **October 1-5**. Plaintiff will be allotted **33 hours** of trial time and Defendants will be
21 allotted **30 hours** of trial time. This schedule should allow the case to get to the jury by
22 the morning of October 4, 2018.

23 **G. Dr. Kandarpa.**

24 Kruse may use Dr. Kandarpa as a witness at trial. *See* Doc. 11320 at 4, ¶ 9.

25
26 ¹ The Court stated that it would propose a new schedule for Plaintiffs' *Cisson*
27 motion if the Mulkey case were to be replaced. Doc. 11549. Plaintiffs have made clear,
28 however, that they do not intend to re-urge the motion regardless of which case is chosen
 for the third bellwether. Doc. 11639 at 3.

1 **III. The Sixth Bellwether: Tinlin.**

2 Defendants propose the King case for the sixth bellwether, and Plaintiffs propose
3 Tinlin. Docs. 11550, 11553. The five cases already selected for bellwether trials consist
4 of three G2 cases (Booker, Kruse, and Hyde) and two Eclipse cases (Jones and Mulkey).
5 The Court agrees with Plaintiffs that it is important to have a Recovery case as one of the
6 six bellwether trials. Doc. 11553 at 2-3. The Tinlin case is the only potential bellwether
7 that involves a Recovery filter. The Court previously found Tinlin to be a strong
8 candidate for a bellwether, but expressed concern that she may not be able to endure the
9 rigors of an out-of-state trial due to her illness. Doc. 5770 at 1-2. Plaintiffs, however,
10 have confirmed that Tinlin is willing and able to travel to Arizona for trial. Doc. 11553
11 at 3.

12 For reasons stated on the record at the ninth case management conference, the
13 Court does not view King as a helpful bellwether case. Doc. 5770 at 2. Defendants do
14 not address those concerns in their memorandum. Moreover, King involves a G2 like
15 three of the other bellwether cases. Defendants assert that the King case is representative
16 of the MDL inventory as a whole because it involves perforation and an unsuccessful
17 retrieval attempt. Doc. 1550 at 2. But even if this were true, the Court finds that it is
18 more important for the sixth bellwether to be a Recovery case.²

19 Trial in the Tinlin bellwether will be held in **May 2019**. The Court will determine
20 the specific trial dates after the Kruse trial.

21 **IV. Disposition of the SNF Cases.**

22 The nearly 100 Simon Nitinol Filter (“SNF”) cases should not be part of this
23 MDL. The SNF is not part of the master complaint, which is limited to Bard retrievable
24 filters. Doc. 364. The SNF cases have been filed by more than 20 different law firms.
25 Defendants do not oppose the request by Plaintiffs’ counsel to have 30 days to obtain

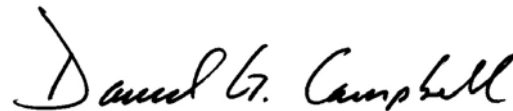
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27 ² Given the selection of Tinlin for the sixth bellwether, the Court need not consider
28 Plaintiffs’ alternative choice, DeWitt. Neither side proposes Nelson, Peterson, or Mixson
 as the final bellwether case.

1 responses from the firms representing the SNF plaintiffs as to what action should be
2 taken in those cases. Doc. 11550 at 4. Plaintiffs shall file a notice regarding the status of
3 the SNF cases by **July 16, 2018**.

4 **V. Remand of the “Mature” Cases.**

5 More than two years ago, the parties estimated that the 10 mature cases would be
6 “ripe for remand in 4-6 months.” Doc. 914 at 2. Since that time, common fact discovery
7 and expert disclosures in this MDL have been completed, and the Court has ruled on
8 *Daubert* motions and Defendants’ summary judgment motion based on preemption. The
9 Court concludes that it is time to remand the mature cases to their home districts. The
10 Court will look into the proper procedure for remand and invite briefing if necessary.

11 Dated this 28th day of June, 2018.

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16 David G. Campbell
17 United States District Judge
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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**

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9 IN RE: Bard IVC Filters Products Liability
10 Litigation,

No. MDL 15-02641-PHX DGC

11 **CASE MANAGEMENT ORDER**
12 **NO. 35**

13
14 As set forth in Case Management Order No. 34, the bellwether cases are scheduled
15 for trial as follows: Kruse (September 2018), Hyde (November 2018), Mulkey (February
16 2019), and Tinlin (May 2019). Doc. 11659 at 1-4. The Court has determined that it must
17 grant summary judgment in favor of Defendants on the claims asserted by Plaintiff
18 Kruse. *See* Doc. 11839. The Court held a conference call with the parties today to
19 discuss scheduling issues and whether the Hyde case could be moved to the September
20 bellwether slot in lieu of the Kruse case. On the basis of the conference, the Court enters
21 the following order:

22 **I. September 2018 Bellwether: Hyde.**

23 The parties agreed that in lieu of Kruse, and with certain scheduling modifications,
24 the Hyde case can be tried in September. The dates and deadlines set forth in Case
25 Management Order No. 34 (Doc. 11659) are modified in part as follows for the Hyde
26 trial:

27 **A. Jury Questionnaire and Selection.**

28 1. By **July 18, 2018**, the parties shall provide the Court with proposed

1 changes to the jury questionnaire used in the Jones trial. The Court will consider these
2 proposals in finalizing the questionnaire for the Hyde trial.

3 2. The Clerk shall mail the questionnaire to 200 jurors no later than
4 **July 20, 2018**. The questionnaire will instruct the prospective jurors to return it to the
5 Court no later than **August 17, 2018**.

6 3. A thumb drive will be prepared for counsel (one for each side)
7 containing copies of the questionnaires and will be available for pickup at the jury office
8 on **August 24, 2018**. The thumb drive and any paper copies made by counsel must be
9 returned to the Court by counsel on the day of jury selection.

10 4. On **August 30, 2018**, the Court will provide the parties with a list of
11 prospective jurors the Court proposes to excuse for hardship on the basis of their
12 responses to the first question in the questionnaire.

13 5. The Court will hold a final pretrial conference in the Hyde case on
14 **September 6, 2018 at 10:00 a.m.** and will address with the parties juror excusals for
15 hardship and challenges for cause. *See* Doc. 11320 at 2, ¶ 2(e).

16 6. On **September 18, 2018, at 9:00 a.m.**, 50 prospective jurors will be
17 called to Court to appear for voir dire. Following voir dire, the Court will hear and rule
18 on challenges for cause. The Court will seat 9 jurors. Each side will have 3 pre-emptory
19 strikes. *See* Doc. 11320 at 2, ¶ 2(f).

20 **B. Motion for Summary Judgment.**

21 The Court will rule on the choice-of-law issue raised in the Hyde summary
22 judgment motion (Doc. 7359) by **July 25, 2017**. The Court will endeavor to rule on the
23 remaining summary judgment issues in Hyde as soon as possible.

24 **C. Motions in Limine.**

25 Motions in limine, limited to three pages each, shall be filed by **August 10, 2018**.
26 Responses to motions in limine, limited to three pages each, shall be filed by
27 **August 24, 2018**. No replies shall be filed.

28 Defendants may, if they so choose, re-urge their motion in limine regarding

1 Recovery death evidence (Doc. 9862) pursuant to the schedule set forth above.
2 Memoranda on this issue may be up to 5 pages long. The parties shall not repeat
3 arguments previously made. The issue was fully briefed for the Booker trial, and the
4 Court has addressed Recovery death evidence in several orders. Docs. 10258, 10819,
5 10920, 11041.¹

6 **D. Deposition Designations.**

7 The parties shall provide deposition designations by **August 22, 2018**.

8 **E. Proposed Final Pretrial Order.**

9 The proposed final pretrial order for the Hyde bellwether shall be submitted by
10 **4:00 p.m. on August 24, 2018**. The Court will enter a separate order governing the
11 materials that should be submitted with the proposed final pretrial order.

12 **F. Trial Days.**

13 The trial dates for the Hyde bellwether will remain the same as those set for
14 Kruse: **September 18-21** and **24-28**, and **October 1-5**. Plaintiff will be allotted
15 **33 hours** of trial time and Defendants will be allotted **30 hours** of trial time. This
16 schedule should allow the case to get to the jury by the morning of October 4, 2018. *See*
17 Docs. 11320 at 3-4, 11659 at 3.

18 **G. Dr. Kandarpa.**

19 Hyde may use Dr. Kandarpa as a witness at trial. *See* Doc. 11320 at 4, ¶ 9.

20 **II. November 2018 Bellwether.**

21 Trial in this bellwether slot will be held on **November 5-9, 13-16, 19-20**, and
22 **26-28**. The parties should note that these dates have been modified (*see* Doc. 11659 at 2)
23 to allow for 14 trial days and account for the federal holiday on November 12 (Veterans
24 Day). The Plaintiff for the fourth bellwether (Mulkey or Tinlin) will be determined after
25

26 ¹ The Court previously stated that it would propose a new schedule for Plaintiffs'
27 *Cisson* motion if a new case were selected for the September 2018 bellwether slot.
28 Doc. 11549. Plaintiffs have made clear, however, that they do not intend to re-urge the
motion regardless of which case is chosen for the third bellwether. Doc. 11639 at 3.

1 the parties file memoranda concerning Mulkey's health condition and the feasibility of
2 Tinlin's case being tried in November.

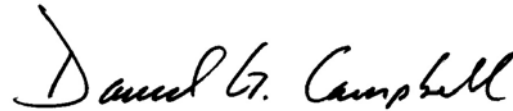
3 **III. February 2019 Bellwether.**

4 Trial in this bellwether slot will be held on **February 11-15, 19-22, 25-28**, and
5 **March 1, 2019**.

6 **IV. May 2019 Bellwether.**

7 The Court will determine whether a sixth bellwether trial should be held, and the
8 specific Plaintiff and dates for such bellwether, after the Hyde trial.

9 Dated this 13th day of July, 2018.

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14 David G. Campbell
15 United States District Judge
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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**
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9 IN RE: Bard IVC Filters Products Liability
10 Litigation,
11 _____

No. MDL 15-02641-PHX-DGC

12 Lisa Hyde and Mark E. Hyde, a married
13 couple,

No. CV-16-00893-PHX-DGC

14 Plaintiffs,

ORDER

15 v.

16 C. R. Bard, Inc., a New Jersey corporation;
17 and Bard Peripheral Vascular, Inc., an
18 Arizona corporation,

19 Defendants.
20 _____

21 This multidistrict litigation proceeding (“MDL”) involves thousands of personal
22 injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular,
23 Inc. (collectively, “Bard”). Bard manufactures and markets medical devices, including
24 inferior vena cava (“IVC”) filters. The MDL Plaintiffs received implants of Bard IVC
25 filters and claim that they are defective and have caused serious injury or death.

26 One of the MDL cases is brought by Plaintiffs Lisa and Mark Hyde. Mrs. Hyde
27 received a Bard filter seven years ago. Her case has been selected as one of several
28 bellwether cases and is set for trial in September 2018. Defendants have filed a motion

1 for partial summary judgment. Doc. 7359. The motion is fully briefed, and the parties
2 agree that oral argument is not necessary. The Court will grant the motion in part and
3 deny it in part.

4 **I. Background.**

5 The IVC is a large vein that returns blood to the heart from the lower body. An
6 IVC filter is a device implanted in the IVC to catch blood clots before they reach the
7 heart and lungs. This MDL involves multiple versions of Bard IVC filters – the
8 Recovery, G2, G2X, Eclipse, Meridian, and Denali. They are spider-shaped devices that
9 have multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with
10 elastic hooks that attach to the IVC wall and curved arms to catch or break up blood clots.
11 Each of these filters is a variation of its predecessor.

12 The MDL Plaintiffs allege that Bard filters are more dangerous than other IVC
13 filters because they have higher risks of tilting, perforating the IVC, or fracturing
14 and migrating to vital organs. Plaintiffs further allege that Bard failed to warn patients
15 and physicians about these higher risks. Defendants dispute these allegations, contending
16 that Bard filters are safe and effective, that their complication rates are low and
17 comparable to those of other IVC filters, and that the medical community is aware of the
18 risks associated with IVC filters.

19 **II. The Hyde Plaintiffs.**

20 The following facts are not disputed for summary judgment purposes. Plaintiff
21 Lisa Hyde has a history of deep vein thrombosis and pulmonary emboli. On February 25,
22 2011, she received a Bard G2X filter while living in Wisconsin.¹ Dr. David Henry

23
24 ¹ The parties disagree on whether Mrs. Hyde's filter was a G2X or Eclipse.
25 Defendants stated that Mrs. Hyde received a G2X filter when she was proposed as a
26 bellwether plaintiff (Doc. 5652 at 6), but they now assert that the device likely was an
27 Eclipse based on hospital sales records, copies of which have not been provided to the
28 Court. Doc. 7359 at 2 n.2. Plaintiffs present medical records and physician testimony
suggesting the filter was a G2X, but their cited documents are incomplete. Doc. 7952
at 1-2 n.1 (citing Doc. 7950 ¶¶ 150, 153, 162-63). The parties agree that the filter type
has no bearing on this motion (*id.*; Doc. 7359 at 2 n.20), and, for ease of reference, this
order will assume the filter was a G2X. By August 10, 2018, the parties shall confer and
report to the Court on whether there is a means for determining the filter type prior to
trial, or whether this will be an issue for the jury.

1 implanted the filter without incident. In May 2014, after Mrs. Hyde and her husband had
2 moved to Nevada, a CT scan showed that the filter had tilted, perforated the IVC wall,
3 and fractured, with one strut lodged in the right ventricle of her heart. The filter and
4 fractured strut were removed in August 2014.

5 Mrs. Hyde and her husband assert various claims against Bard: failure to warn
6 (Counts II and VII), design defects (Counts III and IV), failure to recall (Count VI),
7 misrepresentation and concealment (Counts VIII, XII, and XIII), negligence per se
8 (Count IX), breach of implied warranty (Count XI), fraudulent trade practices (Count
9 XIV), loss of consortium (Count XV), and punitive damages. *See* Doc. 364 (master
10 complaint); Doc. 1, Case No. CV-16-00893 (short-form complaint).²

11 Defendants seek summary judgment on the claims for strict liability design defect,
12 failure to warn, failure to recall, misrepresentation and fraud, and breach of implied
13 warranty. Doc. 7359 at 2-4. Plaintiffs concede that summary judgment is proper on the
14 failure to recall and implied warranty claims. Doc. 7952 at 2 n.2. The Court will deny
15 summary judgment on the strict liability design defect claim, but otherwise will grant
16 Defendants' motion. Defendants do not seek summary judgment on claims for negligent
17 design (Counts IV), negligence per se (Count IX), loss of consortium (Count XV), or
18 punitive damages. These claims, plus strict liability design defect, remain in the case.

19 **III. Choice of Law.**

20 Because Wisconsin is the forum where venue would be proper absent this MDL,
21 the parties agree that Wisconsin's conflict-of-law rules should be used to determine the
22 governing law in this case. Docs. 7359 at 5, 7952 at 3; *see* Doc. 1 at 2, Case No. CV-16-
23 00893 (identifying the Eastern District of Wisconsin as the forum court); *see Love v. Blue*

24
25 ² The master complaint is the operative pleading in this MDL. Doc. 364. It serves
26 as a long-form complaint giving notice, pursuant to Rule 8, of the allegations that
27 Plaintiffs assert generally. Plaintiff-specific allegations are contained in individual short-
28 form complaints and fact sheets. Doc. 249 at 6. The master complaint asserts 17 claims
and seeks both compensatory and punitive damages. Doc. 364 ¶¶ 166-349. The Hydies
are not pursuing claims for manufacturing defect (Counts I and V), breach of express
warranty (Count X), wrongful death (Count XVI), and survival (Count XVII). Doc. 7359
at 2 n.1; Doc. 1 at 4, Case No. CV-16-00893.

1 *Cross & Blue Shield of Ga., Inc.*, 439 F. Supp. 2d 891, 892 (E.D. Wis. 2006) (federal
2 courts “apply the choice-of-law rules of the forum state to determine the applicable
3 substantive law”). Defendants argue that Wisconsin law applies. Doc. 7359 at 6.
4 Plaintiffs argue that Nevada law applies. Doc. 7952 at 3.³

5 Wisconsin employs a two-step choice-of-law analysis. Step one considers
6 whether “the contacts of one state to the facts of the case are so obviously limited and
7 minimal that application of that state’s law constitutes officious intermeddling.” *NCR*
8 *Corp. v. Transp. Ins. Co.*, 823 N.W.2d 532, 535 (Wis. Ct. App. 2012) (quoting *Beloit*
9 *Liquidating Trust v. Grade*, 677 N.W.2d 298, 307 (Wis. 2004)). If neither state’s
10 contacts are insignificant, step two considers several “choice-influencing” factors. *Id.*
11 at 536 (citing *Drinkwater v. Am. Fam. Mut. Ins. Co.*, 714 N.W.2d 568, 576 (Wis. 2006);
12 *Heath v. Zellmer*, 151 N.W.2d 664, 672 (Wis. 1967)).

13 **A. Step One – State Contacts.**

14 In evaluating the contacts with each state, the Court must consider the place of
15 contracting, if any, the place of negotiation of any contract, the place of performance, the
16 location of the subject matter, and the domicile, residence, nationality, place of
17 incorporation, and place of business of the parties. *See NCR Corp.*, 823 N.W.2d at 535
18 (citing *Haines v. Mid-Century Ins. Co.*, 177 N.W.2d 328 (Wis. 1970)); Restatement
19 (Second) of Conflicts § 188. Where tort claims are made, courts also consider the
20 locations of the tortious conduct and the injury. *See id.* at 535-36 & n.2 (citing
21 *Drinkwater*, 714 N.W.2d at 576; *Beloit*, 677 N.W.2d at 307; Restatement § 145).

22 In this case, the places of contracting, negotiation, and performance are not
23 relevant because the parties never entered into a contract. Other factors are relevant.
24 Plaintiffs were residents of Wisconsin when Mrs. Hyde received her Bard filter
25 (Docs. 7950 ¶ 151, 7953 ¶¶ 1-2), her medical conditions leading to the filter implant
26 occurred in Wisconsin (*id.*), and the filter was sold in Wisconsin and implanted by a

27
28 ³ The filter was removed in California, but neither side contends that California law applies.

1 Wisconsin doctor (Doc. 7953 ¶¶ 4, 17). On the other hand, Plaintiffs moved to Nevada
2 after Mrs. Hyde received her filter, the filter’s failure and resulting injuries were
3 discovered in Nevada, and Plaintiffs still reside there. Doc. 7950 ¶ 156. Considering all
4 of these facts, the Court finds that both Wisconsin and Nevada have significant contacts
5 with this case.

6 “Because there is a weak presumption in favor of applying the forum law, the
7 nonforum state’s contacts must be clearly more significant for that state to prevail under
8 this first step.” *NCR Corp.*, 823 N.W.2d at 535 (citing *Drinkwater*, 714 N.W.2d at 576);
9 *see State Farm Mut. Auto. Ins. Co. v. Gillette*, 641 N.W.2d 662, 676 (Wis. 2002); *In re*
10 *Jafari*, 569 F.3d 644, 649 (7th Cir. 2009). Nevada’s contacts with this case are not
11 clearly more significant than Wisconsin’s, but neither are they “so obviously limited and
12 minimal” that application of Nevada law would constitute officious intermeddling.
13 *Beloit*, 677 N.W.2d at 307; *see Drinkwater*, 714 N.W.2d at 576-77 (finding Iowa’s
14 contacts to be significant but not greater than Wisconsin’s where the accident and injuries
15 occurred in Wisconsin and the insurance contract was formed in Iowa); *Love*, 439 F.
16 Supp. 2d at 892 (application of the foreign state’s law “only constitutes ‘officious
17 intermeddling’ if the other state is truly of remote connection to the issues in the case”).
18 As a result, the Court must proceed to step two of the choice-of-law inquiry. *See In re*
19 *Jafari*, 569 F.3d at 649 (“[I]f it is not clear that the nonforum contacts are of greater
20 significance, then the court typically analyzes as a tie-breaker the five choice-influencing
21 factors developed in *Heath*[.]”).

22 Plaintiffs cite *NRC Corp.* and argue that great weight should be given to the
23 location of the tortious conduct and the location of the injury. Doc. 7952 at 5. But the
24 court in *NRC Corp.* did not find these two factors to be “qualitatively stronger” on their
25 own; it found them stronger on the facts of the case before it because they were “the only
26 factors that conclusively weigh[ed] in favor of either [state’s] law[.]” 823 N.W.2d at 538.
27 Here, there are several significant contacts with Nevada and Wisconsin. Moreover,
28 Plaintiffs do not contend that the tortious conduct in this case occurred in Nevada.

1 Plaintiffs' reliance on *Drinkwater* fares no better. Doc. 7952 at 5. The accident
2 and injury in that case occurred in Wisconsin, but the court nonetheless declined to
3 resolve the choice-of-law issue at step one because, as here, the contacts with each state
4 were significant. 714 N.W.2d at 577 ("Iowa's contacts are more than minimal and
5 limited. We therefore turn to apply the five choice-influencing factors." (citation
6 omitted)).

7 Plaintiffs claim that the district court in *Johnson v. Mylan Inc.*, 107 F. Supp. 3d
8 967 (E.D. Wis. 2015), applied the state-contacts analysis and determined that Wisconsin
9 law should apply because the illness, treatment, and death occurred in that state.
10 Doc. 7952 at 5. To the contrary, no choice-of-law analysis was needed in *Johnson*
11 because the parties agreed that Wisconsin law applied. 107 F. Supp. 3d at 970.
12 Moreover, the court made clear that "the law of the forum state governs a tort case unless
13 it is clear that nonforum contacts are more significant." *Id.* (citing *Gillette*, 641 N.W.2d
14 at 675-76); *see Schultz*, 2013 WL 4959007, at *4 (applying the law of Wisconsin where
15 the tortious conduct occurred even though the decedent died in Florida and his widow
16 lived there).

17 **B. Step Two – Choice-Influencing Factors.**

18 Step two considers five factors: (1) predictability of results, (2) maintenance of
19 interstate and international order, (3) simplification of the judicial task, (4) advancement
20 of the forum state's interests, and (5) application of the better rule of law. *See NCR*
21 *Corp.*, 823 N.W.2d at 536 (citing *Drinkwater*, 714 N.W.2d at 576; *Heath*, 151 N.W.2d at
22 672). "The appropriate law, unless the above factors clearly displace it, is the law of the
23 forum." *Sentry Ins. v. Novelty, Inc.*, No. 09-CV-355-SLC, 2009 WL 5087688, at *5
24 (W.D. Wis. Dec. 17, 2009).

25 **1. Predictability of Results.**

26 This factor concerns the parties' expectations as to the legal consequences of the
27 conduct that led them to court. *See Drinkwater*, 714 N.W.2d at 577. Bard's interactions
28 with the physician who implanted Mrs. Hyde's filter occurred in Wisconsin, Bard sold

1 the filter to a Wisconsin hospital, and the filter was implanted while Mrs. Hyde lived in
2 Wisconsin. Doc. 7953 ¶¶ 1-2, 4-5, 17. It was thus reasonable for Bard to expect that
3 Wisconsin law would apply to any product liability claims arising from the filter's use.
4 *See Beloit*, 677 N.W.2d at 308 (corporations are "on notice that, if they choose to transact
5 business in this state, they will be subject to Wisconsin law"); *Schultz v. Glidden Co.*,
6 No. 08-C-919, 2013 WL 4959007, at *4 (E.D. Wis. Sept. 13, 2013) ("[Defendant]
7 purposefully marketed and sold its products to a company doing business in Wisconsin,
8 so the application of Wisconsin law could not have been unexpected."); *Brooks v. Gen.*
9 *Cas. Co. of Wis.*, No. 06-C-0996, 2007 WL 4305577, at *4 (E.D. Wis. Dec. 7, 2007)
10 ("[D]efendants, in the course of doing business in Wisconsin, had no reason to expect
11 that the legal consequence of conduct undertaken there would be wrongful death damages
12 that exceed the limitations set by Wisconsin law."). Conversely, the parties could not
13 reasonably have expected Nevada law to apply to filter-related claims because Plaintiffs'
14 move to Nevada for employment reasons was a "fortuitous happenstance, not a
15 predictable result." *Schultz*, 2013 WL 4959007, at *4. This factor favors application of
16 Wisconsin law.

17 **2. Maintenance of Interstate Order.**

18 This factor is a variation of the "officious intermeddling" test applied at step one.
19 *See Extrusion Dies Indus., LLC v. Cloeren Inc.*, No. 08-CV-323-SLC, 2008 WL
20 4401219, at *4 (W.D. Wis. Sept. 24, 2008). It requires that "a jurisdiction which is
21 minimally concerned defer to a jurisdiction that is substantially concerned." *Drinkwater*,
22 714 N.W.2d at 577; *see Heath*, 151 N.W.2d at 672. Here, as explained above, "both
23 jurisdictions are more than minimally concerned." *Drinkwater*, 714 N.W.2d at 577; *see*
24 *also Love*, 439 F. Supp. 2d at 895 (application of one state's law over another's would
25 not upset interstate order where neither jurisdiction is minimally concerned nor is there
26 an indication of forum shopping). This factor is neutral.

27 ///

28 ///

1 **3. Simplification of the Judicial Task.**

2 This factor is also neutral. A federal court managing an MDL proceeding, like
3 courts sitting in diversity, “can apply one state’s law as easily as another’s.” *Extrusion*,
4 2008 WL 4401219, at *4; *see also Love*, 439 F. Supp. 2d at 895.

5 **4. Advancement of the Forum State’s Interests.**

6 Where “application of forum law will advance the governmental interest of the
7 forum state, this fact becomes a major, though not in itself a determining, factor in the
8 ultimate choice of law.” *Heath*, 151 N.W.2d at 663. Plaintiffs assert that Wisconsin and
9 Nevada have an equal interest in regulating a corporation that has sold a defective
10 product. Doc. 7952 at 7. But this factor focuses on the *forum state’s interests*, not the
11 interests of the foreign jurisdiction. Wisconsin has a strong interest in having its laws
12 applied to corporations transacting business within the state. *See Beloit*, 677 N.W.2d
13 at 308. This factor favors application of Wisconsin law.

14 **5. Application of the Better Rule of Law.**

15 This factor asks which state provides “the ‘better law’ under the circumstances.”
16 *Heath*, 151 N.W.2d at 673. Plaintiffs assert that the interests of justice favor applying the
17 law of the state where Mrs. Hyde was injured and resides, but do not explain why Nevada
18 provides the better rule of law. Doc. 7952 at 7. Defendants contend that Wisconsin’s
19 adoption of a product liability statute in 2011 indicates that the state considers its legal
20 standards the better rule of law, but do not explain why the views of the state legislature
21 control. Doc. 7359 at 9.

22 The Court has difficulty with the task of identifying the “better” law. As one court
23 has noted: “Better for whom? Better in what way?” *Extrusion*, 2008 WL 4401219, at
24 *4. Furthermore, “when the question undoubtedly involves compromises between
25 numerous interested groups, such judgments are best preserved for elected legislators.”
26 *Love*, 439 F. Supp. 2d at 897. The Court need not wrestle long with this difficulty,
27 however, because it appears this factor seeks only to identify laws that are obsolete. *See*
28 *Heath*, 151 N.W.2d at 673 (asking whether law is “outmoded, an unrepealed remnant of a

1 bygone age, [or] ‘a drag on the coattails of civilization’” (citation omitted)). Neither
2 Wisconsin’s nor Nevada’s product liability law can accurately be characterized as
3 “obsolete or senseless[.]” *Id.* The Court therefore concludes that the fifth factor is
4 neutral. *See Gillette*, 641 N.W.2d at 678 (finding this factor neutral where it could not be
5 said that the foreign state’s law “is anachronistic or fails to reflect modern trends”);
6 *Schultz*, 2013 WL 4959007, at *4 (Florida did not provide the better rule of law where
7 Wisconsin’s rule was not “anachronistic, or the vestige of a ‘creed outworn’” (citation
8 omitted)); *Clorox Co. v. S.C. Johnson & Son, Inc.*, 627 F. Supp. 2d 954, 968 (E.D. Wis.
9 2009) (“The court has no basis on which to conclude that California law is somehow
10 anachronistic on this point of law. Therefore, the court finds that the fifth factor does not
11 favor the application of either Wisconsin or California law.”).

12 **C. Conclusion.**

13 The contacts with each state are more than minimal, precluding a decision at step
14 one; none of the step-two factors favors application of Nevada law; and two of the factors
15 favor application of Wisconsin law. The Court therefore will apply Wisconsin law in this
16 case. *See Drinkwater*, 714 N.W.2d at 579-80 (applying Wisconsin law where “[a]ll of
17 the factors either point to the application of Wisconsin law or are neutral”); *Brooks*, 2007
18 WL 4305577, at *6 (applying Wisconsin law where none of the factors favored
19 application of the foreign state’s law).

20 **IV. Summary Judgment.**

21 A party seeking summary judgment “bears the initial responsibility of informing
22 the court of the basis for its motion and identifying those portions of [the record] which it
23 believes demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v.*
24 *Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the moving party
25 shows that there is no genuine dispute as to any material fact and the movant is entitled to
26 judgment as a matter of law. Fed. R. Civ. P. 56(a). Only disputes over facts that might
27 affect the outcome of the suit will preclude summary judgment, and the disputed
28 evidence must be “such that a reasonable jury could return a verdict for the nonmoving

1 party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The evidence must
2 be viewed in the light most favorable to the nonmoving party, *Matsushita Elec. Indus.*
3 *Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), and all justifiable inferences are
4 drawn in that party’s favor because “[c]redibility determinations, the weighing of
5 evidence, and the drawing of inferences from the facts are jury functions,” *Anderson*, 477
6 U.S. at 255.

7 **A. Strict Liability Claims (Counts II and III).**

8 Plaintiffs assert strict liability failure to warn and design defect claims. Doc. 1
9 at 3, Case No. CV-16-00893. Under Wisconsin’s product liability statute, Wis. Stat.
10 § 895.047, a manufacturer is liable where the plaintiff shows the product is “defective in
11 design, or is defective because of inadequate instructions or warnings.” § 895.047(1)(a).
12 A product is defective if its foreseeable risks of harm could have been reduced or avoided
13 by the adoption of a reasonable alternative design or warning, and the omission of such
14 alternative renders the product not reasonably safe. *Id.*; see *Lexington Ins. Co. v. Whesco*
15 *Grp., Inc.*, No. 11-CV-598-BBC, 2013 WL 4454959, at *8 (W.D. Wis. Aug. 16, 2013).

16 The statute provides several defenses. Wis. Stat. § 895.047(3)(a)-(e). Defendants
17 assert three in this motion. Defendants first contend that the G2X filter is presumed to be
18 non-defective under § 895.047(3)(b) because the device was cleared by the Food and
19 Drug Administration (“FDA”). Doc. 7359 at 10-13. Defendants further contend that the
20 strict liability claims are barred under § 895.047(3)(d) because the risks associated with
21 IVC filters are well known and inherent characteristics of the product. *Id.* Finally,
22 Defendants claim that Plaintiffs provide no alternative design or warning as required by
23 § 895.047(1)(a). *Id.*

24 **1. Section 895.047(3)(b): Compliance with Government Standards.**

25 Section 895.047(3)(b) creates a rebuttable presumption that a product is not
26 defective if, at the time of sale, it complied with “relevant standards, conditions, or
27 specifications adopted or approved by a federal or state law or agency[.]” The design of
28 the G2X filter and the warnings provided with the device are presumed to be non-

1 defective, Defendants contend, because Bard complied with the FDA’s 510(k) process.
2 Docs. 7359 at 12. Defendants claim that Plaintiffs cannot rebut the presumption. *Id.*

3 Cases have held that § 895.047(3)(b) creates no rebuttable presumption for
4 medical devices cleared under 510(k) review because that review does not concern the
5 safety of the product. *See Hall v. Boston Sci. Corp.*, No. 2:12-CV-08186, 2015 WL
6 874888, at *2 (S.D. W. Va. Feb. 27, 2015) (“510(k) is not a ‘relevant standard’ here.
7 Section 895.047 concerns whether a defect rendered the product ‘unreasonably
8 dangerous,’ § 895.047(1), and, as the Supreme Court has held, 510(k) compliance does
9 not go to the safety of a product.”); *Williams v. Boston Sci. Corp.*, No. 2:12-CV-02052,
10 2016 WL 1448860, at *3 (S.D. W. Va. Apr. 12, 2016) (same). Defendants argue that
11 these cases were wrongly decided. Doc. 8392 at 5. The Court does not agree.

12 Under Wisconsin’s statute, a product is defective only if it is “not reasonably
13 safe.” Wis. Stat. § 895.047(1)(a). The 510(k) clearance process, however, “is focused on
14 *equivalence*, not safety.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) (emphasis in
15 original). The FDA does not approve the product or make a determination that the device
16 is safe and effective; it finds only that the product is substantially equivalent to a
17 predicate device. *See* 21 U.S.C. § 360c(f)(1)(A); 21 C.F.R. § 807.97 (510(k) clearance
18 “does not in any way denote official approval of the device”); *Riegel v. Medtronic, Inc.*,
19 552 U.S. 312, 323 (2008) (citing *Lohr* and noting that “products entering the market
20 through 510(k) may be marketed only so long as they remain substantial equivalents of
21 the relevant [predicate] devices as a qualification for an exemption [from federal safety
22 review] rather than a requirement”); *Hovey v. Cook Inc.*, 97 F. Supp. 3d 836, 845 (S.D.
23 W. Va. Apr. 1, 2015) (510(k) review “is predominantly relative, and the FDA does not
24 engage in an independent investigation of the medical device’s safety and effectiveness”).

25 Because the 510(k) clearance process focuses on equivalence, not safety, the
26 presumption of non-defectiveness afforded by § 895.047(3)(b) is not applicable. Given
27
28

1 this ruling, the Court need not determine whether Plaintiffs’ have presented sufficient
2 evidence to rebut the presumption. *See* Doc. 7952 at 9.⁴

3 **2. Section 895.047(3)(d): Known and Inherent Characteristics.**

4 Section 895.047(3)(d) requires dismissal of strict liability claims where the harm
5 was caused by “an inherent characteristic of the product that would be recognized by an
6 ordinary person with ordinary knowledge common to the community that uses or
7 consumes the product.” Defendants contend that the complications associated with IVC
8 filters – migration, tilt, perforation, and fracture – are inherent characteristics of the
9 device and are well known in the medical community. Doc. 7359 at 10-13. Defendants
10 rely on guidelines published by the Society of Interventional Radiology, a 2010 FDA
11 safety alert, and testimony from the implanting physician and one of Plaintiffs’ experts to
12 show that the types of complications experienced by Mrs. Hyde were widely known
13 before the implant procedure. *Id.* at 10-11.

14 Plaintiffs acknowledge that IVC filters experience adverse events, but contend that
15 Bard’s own analysis shows that the G2-line of filters experienced adverse events at rates
16 higher than other IVC filters. Doc. 7952 at 10. Plaintiffs argue that these increased risks
17 were not known and inherent characteristics of the product. *Id.* at 11.

18 Defendants challenge Plaintiffs’ rate calculations as inaccurate, but this dispute
19 simply creates a triable issue of fact. Doc. 8392 at 6-7. Defendants have not shown that
20 they are entitled to summary judgment based on the defense provided by § 895.047(3)(d).

21 **3. Section 895.047(1)(a): Alternative Design and Warning.**

22 Section 895.047(1)(a) requires the plaintiff to show that the harm posed by the
23 product could have been reduced or avoided with a reasonable alternative design or
24 warning. Defendants claim that Plaintiffs provide no such alternatives. Doc. 7359
25 at 11-13. The Court does not agree.

26
27 ⁴ Defendants assert that the presumption applies even if the government standard
28 is not safety, but cite no legal authority in support. Doc. 8392 at 5.

1 **a. Design Defect.**

2 Plaintiffs’ expert, Dr. Robert McMeeking, has testified that Bard could have
3 developed caudal anchors and penetration limiters sooner than it did. Doc. 7973 at 32.
4 These safety features ultimately were incorporated into Bard’s Meridian and Denali
5 filters, and Bard knew as early as March 2006 that one of its competitors had designed
6 anchors to reduce caudal (downward) migration by flipping two of the hooks that secured
7 the filter to the IVC wall. Doc. 7950 ¶ 87 (Ex. 80). A jury reasonably could conclude
8 from this evidence that specific and reasonable alternative design changes were available
9 when Defendants developed the G2X filter.

10 Defendants note in their reply that Dr. McMeeking does not specify all of the
11 changes that should have been made to the G2X and that Plaintiffs themselves claim the
12 Meridian to be defective even with caudal anchors. Doc. 8392 at 8. But Defendants do
13 not explain why this entitles them to summary judgment. A manufacturer may be liable
14 under § 895.047(1)(a) where the alternative design would have “reduced” the harm posed
15 by the product. Plaintiffs present evidence that caudal anchors help reduce filter
16 migration, which can lead to other complications like those experienced by Mrs. Hyde
17 (tilt, perforation, and fracture). Plaintiffs have presented sufficient evidence of a
18 reasonable alternative design to survive summary judgment.⁵

19 **b. Warning Defect.**

20 Defendants contend that the warning defect claim fails because Plaintiffs identify
21 no “alternative warnings that would have rendered Bard’s filter ‘safe.’” Doc. 7359 at 13.
22 But this is not the standard. The alternative warning need not render the product safe;
23 instead, the plaintiff must show that the warning “could have . . . reduced or avoided” the

24
25 ⁵ The parties dispute whether Bard’s Simon Nitinol filter (“SNF”) can serve as an
26 alternative design. Defendants contend that the SNF is a purely permanent filter and,
27 therefore, not a reasonable alternative for the retrievable G2X. Docs. 7359 at 12 n.6
28 (citing *Godoy v. E.I. du Pont de Nemours & Co.*, 743 N.W.2d 159, 162 (Wis. Ct. App.
2009) (the alternative design cannot make the product “something else”)). Plaintiffs
counter that the SNF is a suitable alternative because the G2X can also serve as a
permanent device and its optional retrievability is not a functional element. Doc. 7952
at 16-17. Given the ruling above, the Court need not resolve this issue for purposes of
summary judgment.

1 harm and that the warning's omission "renders the product not reasonably safe." Wis.
2 Stat. § 895.047(1)(a); *see Lexington*, 2013 WL 4454959, at *8.

3 Plaintiffs assert that the G2X filter's IFU should have disclosed "the *increased*
4 risk of adverse events when compared to the SNF and competitor filters." Doc. 7952 at
5 21 (emphasis in original). Whether this proposed warning could have reduced or avoided
6 the harm caused by the G2X filter, and whether omission of the warning renders the G2X
7 defective, are questions best resolved by the jury. As explained below, however,
8 Plaintiffs' strict liability failure to warn claim (Count II) fails for lack of causation.

9 **B. Failure to Warn Claims (Counts II and VII).**

10 Defendants contend that the negligent failure to warn claim is barred by the
11 learned intermediary and sophisticated user doctrines.⁶ Doc. 7359 at 13-15. Defendants
12 further contend that the warnings Bard provided with the G2X were adequate as a matter
13 of law. *Id.* at 15-16. Finally, Defendants argue that Plaintiffs' strict liability and
14 negligent failure to warn claims fail because the alleged inadequate warning was not the
15 proximate cause of Mrs. Hyde's injuries. *Id.* at 17-18 & n.8. Plaintiffs contend that
16 Wisconsin does not apply the learned intermediary doctrine and that Bard's warnings
17 were inadequate, but do not address causation. Doc. 7952 at 18-22.

18 The Court can resolve these claims on the element of causation. Regardless of
19 whether Bard's duty to warn extended to Dr. Henry or Mrs. Hyde, Plaintiffs have failed
20 to present any evidence that an inadequate warning caused Mrs. Hyde's injuries, as
21 required under Wisconsin law. *See* Wis. Stat. § 895.047(1)(e) (requiring a plaintiff to

22
23 ⁶ The Wisconsin Supreme Court has not decided whether to adopt the
24 learned intermediary doctrine, and federal courts applying Wisconsin law are split on the
25 issue. *Compare Maynard v. Abbott Labs.*, No. 12-C-0939, 2013 WL 695817 (E.D. Wis.
26 Feb. 26, 2013) ("Wisconsin does not apply the learned intermediary doctrine"), and *Forst v.*
27 *SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 968 (E.D. Wis. 2009) (declining to
28 apply the doctrine absent some indication that the Wisconsin Supreme Court would do
so), *with In re Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746, 751-52
(7th Cir. 2018) (concluding that the Wisconsin Supreme Court would adopt the doctrine),
Monson v. Acromed Corp., No. 96-C-1336, 1999 WL 1133273, at *20 (E.D. Wis.
May 12, 1999) ("manufacturers have a duty to warn only the treating physician"), and
Lukaszewicz v. Ortho Pharm. Corp., 510 F. Supp. 961, 963 (E.D. Wis. 1981) (noting that
"the provision of proper warnings to a physician will satisfy the manufacturer's duty to
warn").

1 prove that “the defective condition was a cause” of her injuries); *Kessel v. Stansfield*
2 *Vending, Inc.*, 714 N.W.2d 206, 211-12 (Wis. Ct. App. 2006) (a plaintiff claiming
3 negligent failure to warn must prove “a causal connection between the defendant’s breach
4 of the duty of care and the plaintiff’s injury”); *Kurer v. Parke, Davis & Co.*, 679 N.W.2d
5 867, 876 (Wis. Ct. App. 2004) (“A plaintiff who has established both a duty and a failure
6 to warn must also establish causation by showing that, if properly warned, he or she
7 would have altered behavior and avoided injury.”).

8 Plaintiffs argue at length that Bard’s warnings for the G2X were inadequate, but
9 present no evidence or argument that an adequate warning would have prevented use of
10 the Bard filter in this case. Doc. 7592 at 19-22; *see* Doc. 8392 at 12. Plaintiffs identify
11 no evidence suggesting that Mrs. Hyde would have chosen not to receive a G2X filter had
12 she been informed the device had an increased risk of adverse events relative to other
13 IVC filters. Nor do Plaintiffs present evidence from which a reasonable inference can be
14 drawn that an adequate warning would have altered Dr. Henry’s decision to use a G2X
15 filter. Dr. Henry testified that he did not remember Mrs. Hyde, was not even sure that the
16 filter implanted in her was a G2X, was not certain who made the decision to use a G2X,
17 and had no independent recollection of the procedure, his thought processes, or what may
18 have been explained to Mrs. Hyde regarding potential risks and treatment options.
19 Doc. 7012 at 5, 8, 18-22, 25. Dr. Henry further testified that he tended to trust the FDA
20 more than individual companies and simply did not know whether he would have
21 considered information about complication rates among filters in making the treatment
22 decision for Mrs. Hyde. *Id.* at 10, 13-14. With respect to the Everest clinical study for
23 the G2 filter, Dr. Henry testified that he “may or may not have been swayed by its
24 content” had he read about it. *Id.* at 16.

25 Plaintiffs argue that there is sufficient evidence that Dr. Henry would have altered
26 his treatment of Mrs. Hyde had he been warned about the risks of Bard filters. Doc. 7953
27 ¶ 15. But the portion of Dr. Henry’s deposition relied on by Plaintiffs (*id.* (citing pages
28 44, 45, and 47)) do not support Plaintiffs’ argument. When asked whether he would have

1 found “useful” the fact that “Bard determined its Recovery filter migrated three times
2 more than the industry average,” Dr. Henry testified: “Right or wrong, I felt that the risks
3 for all of the FDA-approvable devices were – were reasonable and customary, and that I
4 probably wouldn’t have deferred or postponed the filter placement in a patient who I felt
5 really needed it.” Doc. 7012 at 44-45. The following exchange then occurred:

6 Q. As I’m understanding your answer, right or wrong, you assumed that
7 the complication rates among the FDA cleared or approved IVC
8 filters was roughly equivalent?

9 A. Yes.

10 Q. If you had learned differently, that would be the type of information
11 that you would have used in your clinical practice, true?

12 * * *

13 THE WITNESS: I tend to trust the FDA more than individual companies.

14
15 *Id.* at 45.

16 Plaintiffs’ counsel continued to press:

17 Q. Based on your practice of medicine back in 2011, when you’re
18 making the decision about which device to implant in a patient’s
19 body, you – is it your testimony that you wouldn’t be concerned with
20 how frequently those fail?

21 * * *

22 THE WITNESS: It was my understanding that the complication rates were
23 low. And, as a physician, you have to look at the big picture. And I
24 think that the – all of the devices were meeting the expectations of
25 the FDA, and I didn’t see any deciphering thing to persuade me one
26 way or the other.

27 *Id.* at 48.

28 Plaintiffs argue that Dr. Henry referred to FDA “approval” of a product and
obviously did not understand that 510(k) review results only in “clearance.” Doc. 7953 at

1 5-6. This is not entirely correct. As quoted above, counsel posed questions in terms of
2 FDA clearance or approval. Doc. 7012 at 44-45. But even if true, this fact does not
3 provide what is missing in Dr. Henry’s testimony – that a warning of greater risks would
4 have affected his decision to use a G2X filter. Plaintiffs also cite the deposition
5 testimony quoted immediately above, focusing particularly on Dr. Henry’s statement that
6 “I didn’t see any deciphering thing to persuade me one way or the other.” *Id.* at 48. But
7 this statement was made right after he said “all of the devices were meeting the
8 expectations of the FDA” (*id.*), and does not constitute evidence that he would have acted
9 differently had he received some different warning from Bard. Finally, Plaintiffs
10 complain that Dr. Henry’s counsel instructed him not to answer questions about how he
11 would have reacted to facts found in various Bard internal documents (Doc. 7953 at 6),
12 but the Court previously held that this instruction was proper under Wisconsin law
13 (Doc. 8180).

14 Because Plaintiffs present no evidence that Mrs. Hyde or Dr. Henry would have
15 acted differently in the face of different warnings by Bard, summary judgment is
16 warranted on the failure to warn claims. *See Kurer*, 679 N.W.2d at 876 (“Absent proof
17 that a more complete or explicit warning would have prevented Kurer’s use of Loestrin,
18 she cannot establish that [the] alleged failure to warn was the proximate cause of her
19 injuries.”); *Menges*, 61 F. Supp. 2d at 830 (“[A] plaintiff must not only show that the
20 manufacturer’s warning was inadequate, but that such inadequacy affected the
21 prescribing physician’s use of the product and thereby injured the plaintiff.”); *Hanson v.*
22 *Boston Sci. Corp.*, No. 2:13-CV-10653, 2016 WL 1448868, at *5 (S.D.W. Va. Apr. 12,
23 2016) (applying Wisconsin law and finding the causation evidence insufficient where it
24 “require[d] a reasonable juror to speculate, based only on mere *possibility*, that [the
25 doctor] would have altered her decision to prescribe the product simply because she
26 would have *considered* an additional factor in her risk/benefit calculus” (emphasis in
27 original)).

28 ///

1 **C. Misrepresentation and Fraud Claims (Counts VIII and XII-XIV).**

2 Plaintiffs assert claims for negligent and fraudulent misrepresentation, fraudulent
3 concealment, and fraudulent trade practices in violation of Wis. Stat. § 100.18. Doc. 364
4 ¶¶ 218-28, 245-321. The parties agree that an essential element of each of these claims
5 is reliance or causation. Doc. 7592 at 22. Defendants argue that summary judgment is
6 warranted because there is no evidence showing that Mrs. Hyde or Dr. Henry relied on
7 any representations by Bard or that Bard's public statements caused Mrs. Hyde's injuries.
8 Docs. 7359 at 19-20. The Court agrees.

9 Mrs. Hyde admits that she never spoke to anyone at Bard or received any
10 information from Bard. Doc. 7953 ¶ 27. She presents no evidence that Dr. Henry relied
11 on any information Bard provided about its IVC filters, through its sales force or
12 otherwise. Dr. Henry testified that he tends to trust the FDA more than individual
13 companies and was comfortable using FDA-approved medical devices. Doc. 7950 ¶ 181.
14 Absent some evidence Dr. Henry or Mrs. Hyde relied on representations made by Bard,
15 or that Bard's alleged concealment of information caused Plaintiffs' injuries, the fraud
16 and misrepresentation claims fail as a matter of law. *See Staudt v. Artifex Ltd.*, 16 F.
17 Supp. 2d 1023, 1030 (E.D. Wis. 1998) (misrepresentation and concealment claims
18 require reliance resulting in damage).

19 Plaintiffs contend that Bard committed fraud on the FDA, and that Dr. Henry's
20 trust in the FDA constitutes reliance on Bard's misrepresentations and concealment.
21 Doc. 7952 at 22-24. But Plaintiffs present no legal authority to support this contention,
22 and any claim based solely on fraud on the FDA is preempted. *See Buckman Co. v.*
23 *Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). Plaintiffs' misrepresentation and
24 fraud claims fail for lack of reliance and causation.

25 **IT IS ORDERED:**

26 1. The following claims are **dismissed** based on Plaintiffs' withdrawal of the
27 claims before Defendants moved for summary judgment: manufacturing defect (Counts I
28 and V) and breach of express warranty (Count X).

1 2. Defendants' motion for partial summary judgment (Doc. 7359) is **granted**
2 **in part and denied in part**. The motion is granted with respect to Plaintiffs' claims for
3 failure to warn (Counts II and VII), failure to recall (Count VI), misrepresentation,
4 concealment, and fraud (Counts VIII and XII-XIV), and breach of implied warranty
5 (Count XI). The motion is denied with respect to the strict liability design defect claim
6 (Count III). This claim, along with the claims for negligent design (Count IV),
7 negligence per se (Count IX), loss of consortium (Count XV), and punitive damages,
8 remain for trial.

9 3. By **August 10, 2018**, the parties shall confer and provide a joint report to
10 the Court on whether there is a means for determining Mrs. Hyde's filter type prior to
11 trial, or whether this will be an issue for the jury to decide.

12 Dated this 26th day of July, 2018.

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17 David G. Campbell
18 United States District Judge
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1 **WO**

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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**

8
9 IN RE: Bard IVC Filters Products Liability
10 Litigation,

No. MDL 15-02641-PHX DGC

11 **CASE MANAGEMENT ORDER**
12 **NO. 36**
13

14 The Court has reviewed the parties' memoranda on Plaintiff Debra Mulkey's
15 status and the possibility of trying the Tinlin case in November 2018. Docs. 11951,
16 11952. The memorandum on Ms. Mulkey makes clear that her case should not be
17 scheduled for trial in November. She continues to undergo medical testing attempting to
18 identify the cause of her concerning health issues, and scheduling her for the stress of a
19 three-week trial in November would be unwise. The Court will try Ms. Mulkey's case in
20 2019.

21 The Court had fully intended to try a fourth bellwether trial in November, but the
22 Court's grant of summary judgment in the Kruse case and the unavailability of
23 Ms. Mulkey for trial this year mean that the only remaining bellwether plaintiff is Debra
24 Tinlin. Unfortunately, much of the case-specific discovery and expert disclosures
25 required for the Tinlin trial have not been completed. Plaintiffs propose an aggressive
26 schedule to have the Tinlin case ready for trial in November, but the Court concludes that
27 the schedule is unrealistic. A year's worth of medical records for Plaintiff Tinlin's many
28 medical conditions will need to be collected, many treating physicians likely will need to

1 be deposed, plaintiff-specific expert reports must be prepared and disclosed, expert
2 depositions must be completed, and *Daubert* and summary judgment motions must be
3 briefed and decided. For a trial to begin on November 5, 2018, the Court would need to
4 rule on the *Daubert* and summary judgment motions in early October, something that
5 would be very difficult in light of the Court's administrative responsibilities that month
6 and the fact that the Hyde bellwether trial will not end until October 5.

7 The Court is reluctant to lose the November bellwether trial slot, but
8 circumstances make a Tinlin trial in November unreasonable. As a result, the Court will
9 plan to try the Tinlin and Mulkey cases in February and May of 2019. The Court will
10 decide the order of the trials, and the dates for the trial in May, after the Hyde trial.

11 The parties shall follow this schedule in preparing the Tinlin case for trial:

12 1. Plaintiff shall provide an updated provider list and executed medical
13 authorizations to Defendants by **August 10, 2018**.

14 2. The parties shall obtain updated medical records from known treaters and
15 newly identified treaters by **September 28, 2018**.

16 3. The parties shall identify treating physicians and fact witnesses to be
17 deposed, and shall complete the depositions on a rolling basis, by **October 5, 2018**.

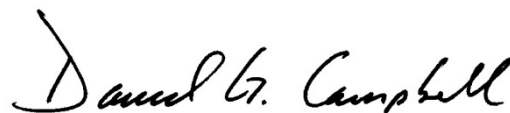
18 4. Plaintiff's case-specific expert disclosures shall be completed by
19 **September 28, 2018**.

20 5. Defendants' case-specific expert disclosures shall be completed by
21 **October 26, 2018**.

22 6. Case-specific experts shall be deposed by **November 16, 2018**.

23 7. Dispositive and *Daubert* motions shall be filed by **December 7, 2018**,
24 responses by **December 28, 2018**, and replies by **January 11, 2019**.

25 Dated this 2nd day of August, 2018.

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David G. Campbell
United States District Judge

1 **WO**

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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**
8

9 IN RE: Bard IVC Filters Products Liability
10 Litigation,
11 _____

No. MDL 15-02641-PHX-DGC

12 Carol Kruse, an individual,
13 Plaintiff,

No. CV-15-01634-PHX-DGC

14 v.

ORDER

15 C. R. Bard, Inc., a New Jersey corporation;
16 and Bard Peripheral Vascular, Inc., an
17 Arizona corporation,
18 Defendants.
19 _____

20 This multidistrict litigation proceeding (“MDL”) involves thousands of personal
21 injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular,
22 Inc. (collectively, “Bard”). Bard manufactures and markets medical devices, including
23 inferior vena cava (“IVC”) filters. The MDL Plaintiffs have received implants of Bard
24 IVC filters and claim that they are defective and have caused Plaintiffs to suffer serious
25 injury or death.

26 One of the MDL cases is brought by Plaintiff Carol Kruse, who had a Bard filter
27 implanted nine years ago. Ms. Kruse’s case has been selected as one of several
28 bellwether cases. Defendants have filed a motion for summary judgment. Doc. 7341.

1 The motion is fully briefed, and the parties agree that oral argument is not necessary. The
2 Court will grant the motion.

3 **I. Background.**

4 The IVC is a large vein that returns blood to the heart from the lower body. An
5 IVC filter is a device implanted in the IVC to catch blood clots before they reach the
6 heart and lungs. This MDL involves multiple versions of Bard IVC filters – the
7 Recovery, G2, G2X, Eclipse, Meridian, and Denali. These are spider-shaped devices that
8 have multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with
9 hooks that attach to the IVC wall and curved arms to catch or break up blood clots. Each
10 of these filters is a variation of its predecessor.

11 The MDL Plaintiffs allege that Bard filters are more dangerous than other IVC
12 filters because they have higher risks of tilting, perforating the IVC, or fracturing
13 and migrating to vital organs. Plaintiffs further allege that Bard failed to warn patients
14 and physicians about these higher risks. Defendants dispute these allegations, contending
15 that Bard filters are safe and effective, that their complication rates are low and
16 comparable to those of other IVC filters, and that the medical community is aware of the
17 risks associated with IVC filters.

18 **II. Plaintiff Carol Kruse.**

19 Plaintiff Kruse has a history of blood clots. Before knee surgery in July 2009, she
20 had a Bard G2 filter implanted to mitigate the risk of a pulmonary embolism during or
21 after surgery. Dr. Shanon Smith implanted the filter without incident. Dr. Smith
22 attempted to remove the filter on April 7, 2011, but was unsuccessful because the filter
23 had tilted and perforated the IVC wall. The filter remains embedded in Plaintiff's IVC.

24 Plaintiff filed suit against Bard on April 6, 2015. She asserts various claims under
25 Nebraska law.¹ The following claims remain: failure to warn (Counts II and VII), design
26 defects (Counts III and IV), failure to recall (Count VI), misrepresentation (Counts VIII

27
28 ¹ The parties agree that Nebraska law applies to Plaintiff's claims. Docs. 7348
at 18 n.7, 8009 at 3 & n.2.

1 and XII), negligence per se (Count IX), concealment (Count XIII), consumer fraud and
2 unfair trade practices (Count XIV), and punitive damages. *See* Doc. 364 (master
3 complaint).²

4 Defendants move for summary judgment on various grounds. Doc. 7348.
5 Plaintiff opposes the motion. Doc. 8009. For reasons stated below, the Court will grant
6 summary judgment on statute of limitations grounds.³

7 **III. Summary Judgment Standard.**

8 A party seeking summary judgment “bears the initial responsibility of informing
9 the court of the basis for its motion and identifying those portions of [the record] which it
10 believes demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v.*
11 *Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the moving party
12 shows that there is no genuine dispute as to any material fact and the movant is entitled to
13 judgment as a matter of law. Fed. R. Civ. P. 56(a). The evidence must be viewed in the
14 light most favorable to the nonmoving party, *Matsushita Elec. Indus. Co. v. Zenith Radio*
15 *Corp.*, 475 U.S. 574, 587 (1986), and all justifiable inferences are drawn in that party’s
16 favor because “[c]redibility determinations, the weighing of evidence, and the drawing of
17 inferences from the facts are jury functions,” *Anderson v. Liberty Lobby, Inc.*, 477 U.S.
18 242, 255 (1986). To avoid summary judgment, the factual dispute must be genuine – that
19 is, the evidence must be sufficient for a reasonable jury to return a verdict for the
20 nonmoving party. *Anderson*, 477 U.S. at 248.

21
22
23 ² The master complaint is the operative pleading in this MDL. It asserts 17 claims
24 and seeks both compensatory and punitive damages. *Id.* ¶¶ 166-349. The allegations and
25 claims asserted in the master complaint have been deemed pled in Plaintiff’s previously
26 filed individual complaint. Doc. 1485 at 1; *see* Doc. 1, Case No. 15-CV-01634-PHX-
DGC. Plaintiff is not pursuing the claims for manufacturing defect (Counts I and V),
breach of warranty (Counts X and XI), loss of consortium, wrongful death, and survival
(Counts XV-XVII). Doc. 8009 at 2 n.1.

27 ³ This bellwether case was set for trial in September 2018. Doc. 11659. In
28 mid-July, the Court informed the parties that it had concluded that summary judgment
must be granted in favor of Defendants. Doc. 11839. The Court stated that it would
issue an order granting summary judgment and setting forth its analysis. *Id.* This is the
order.

1 **IV. Discussion.**

2 **A. Nebraska's Statute of Limitations and Discovery Rule.**

3 Under Nebraska law, civil actions generally must be brought within the time
4 period prescribed by the applicable statute of limitations. Neb. Rev. Stat. § 25-201.
5 Nebraska's statute of limitations for product liability actions requires that such actions,
6 other than asbestos-related suits, "be commenced within four years next after the date on
7 which the death, injury, or damage complained of occurs." Neb. Rev. Stat. § 25-224(1).

8 Nebraska courts have adopted a discovery rule for § 25-224(1). *See Condon v.*
9 *A. H. Robins Co.*, 349 N.W.2d 622, 623-27 (1984). Under this rule, an injury "occurs"
10 within the meaning of the statute, and the limitations period begins to run, when the
11 plaintiff first "discovers, or in the exercise of reasonable diligence should have
12 discovered, the existence of [the] injury[.]" *Id.* at 627. "Discovery refers to the fact that
13 one knows of the existence of an injury . . . and not that one knows who or what may
14 have caused that injury[.]" *Thomas v. Countryside of Hastings, Inc.*, 524 N.W.2d 311,
15 313 (Neb. 1994). Similarly, "one need not know the full extent of one's damages before
16 the limitations period begins to run[.]" *Gordon v. Connell*, 545 N.W.2d 722, 726
17 (Neb. 1996).

18 **B. Plaintiff's Claims Are Time Barred Under § 25-224(1).**

19 Because Plaintiff filed suit on April 6, 2015, her claims are time barred if the four-
20 year limitations period set forth in § 25-224(1) began to run on or before April 5, 2011.
21 Defendants argue that Plaintiff discovered her injury no later than March 14, 2011,
22 when Plaintiff underwent a pre-op exam before the attempted removal of the G2 filter.
23 Doc. 7348 at 6-8. Plaintiff contends that her claims are timely because she did not
24 discover her injury until after the removal procedure on April 7, 2011. Doc. 8009 at 5-8.

25 The Court agrees with Defendants. The undisputed evidence shows that Plaintiff
26 clearly knew of the existence of the injury well before then. Plaintiff began experiencing
27 new and unfamiliar abdominal pain only a few days after the filter was implanted in
28 2009. Doc. 7350-4 at 12. Plaintiff had not felt this pain before the filter was implanted,

1 *id.*, and she continued to have occasional abdominal pain when she twisted and bent
2 certain ways, *id.* at 18. The abdominal pain was not related to digestive problems or
3 Plaintiff's low back pain. *Id.* at 17-18.

4 Sometime in 2009 or 2010, Plaintiff saw a TV ad with a phone number for people
5 with IVC filters to call if they were having "problems" with their filters. *Id.* at 4-8;
6 Doc. 7350-1 at 4. Plaintiff called the number. Doc. 7350-4 at 3-5.

7 In late 2010, Plaintiff discussed her abdominal pain and the fact that she had an
8 IVC filter with Kristi Eggers, a nurse who worked with local doctors and with Plaintiff at
9 a nursing home. *Id.* at 13. Plaintiff testified about her conversation with Eggers as
10 follows:

11 Q. When is the first time you remember speaking to a doctor about
12 having your IVC filter removed after it was implanted?

13 A. That would have been – her name is Kristi Eggers, and she was [a]
14 nurse practitioner *And in our conversation I told her that I had*
15 *a filter, and, you know, I had this infrequent pain,* and she said,
16 "Well, you know, can you have the filter removed?" And that's kind
17 of how we got to talking about it. So I called Dr. Smith and said
let's see if we can get it out.

18 Doc. 7350-4 at 13-14 (emphasis added).

19 Plaintiff underwent a pre-op exam on March 14, 2011. Doc. 7350-2 at 13-15.
20 The progress note for that exam, signed by Eggers, states: "[Patient] is planning to have
21 [the] IVC filter removed. This has been causing her pain for the last 3-4 months."
22 Doc. 7350-2 at 13. When shown this progress note during her deposition, Plaintiff did
23 not dispute that it said the G2 filter had been causing her pain. *Id.* at 16. The following
24 exchange then occurred:

25 Q. At this time period you were experiencing the abdominal pain that
26 you described before where it would hurt when you twisted or bent
27 certain ways; right?

28 A. Correct.

1 Q. And you were going in to get this pre-op clearance to have your IVC
2 filter removed?

3 A. Yes.

4 Q. And at this time period you had had conversations with Kristi Eggers
5 about potentially my IVC filter is causing that pain; right?

6 A. Yes, abdominal pain.
7

8 *Id.* at 18-19.

9 This evidence shows that Plaintiff knew of her abdominal pain before the removal
10 procedure on April 7, 2011, and even suspected that it was caused by the G2 filter. For
11 purposes of § 25-224(1), Plaintiff discovered the existence of her injury – and the
12 limitations period began to run – more than four years before she filed suit. *See Alston v.*
13 *Hormel Foods Corp.*, 730 N.W.2d 376, 385 (Neb. 2007) (explaining that the discovery
14 rule tolls the statute of limitations only where the plaintiff “is wholly unaware that he or
15 she has suffered an injury or damage”). The Court will grant Defendants’ summary
16 judgment motion on statute of limitations grounds. *See Gordon*, 545 N.W.2d at 726
17 (affirming summary judgment and finding that the plaintiff discovered his injury within
18 the limitations period where “he certainly knew that he had been injured, because he
19 continued to experience pain”).

20 Plaintiff contends that the date she discovered her injury is a disputed issue of fact
21 that should be left to the jury. Doc. 8009 at 5. But Plaintiff does not dispute the facts set
22 forth above. *See* Doc. 7959 ¶¶ 6-7, 13-15. Those facts, even when construed in her
23 favor, show that Plaintiff experienced previously unknown pain after the filter implant,
24 continued to have the pain, albeit infrequently, called the IVC number designated for
25 people with filter problems, mentioned the pain to Kristi Eggers, suggested to Eggers that
26 the pain was caused by the filter, and scheduled an appointment to have the filter
27 removed. When Plaintiff met with Eggers before the removal procedure on March 14,
28 2011, Eggers stated in the progress note that the filter “has been causing her pain for the

1 last 3-4 months.” Doc. 7350-2 at 13. No jury reasonably could find that Plaintiff first
2 discovered her injury on April 7, 2011.

3 In claiming that she “neither knew nor had reason to know that her pain was
4 filter-related in March 2011,” Plaintiff cites the following exchange at the end of her
5 deposition:

6 Q. Did you know or have reason to know that pain was filter related in
7 March of 2011?

8 A. No.

9 Q. When was the first time that you had any reason to believe that your
10 filter was – there is anything wrong with your filter?

11 A. When the filter retrieval was unsuccessful and Dr. Smith came in
12 and said, you know, the filter is tilted and that’s why we couldn’t get
13 it out.

14 Docs. 7959 at 6, 8009 at 6 (citing Doc. 7959-1 at 27). These statements contradict her
15 prior testimony about the G2 filter causing her abdominal pain and the March 2011
16 progress note. The statements do not present “a sufficient disagreement to require
17 submission to a jury.” *Kennedy v. Applause, Inc.*, 90 F.3d 1477, 1481 (9th Cir. 1996)
18 (quoting *Anderson*, 477 U.S. at 251-52); see *Craig v. Cty. of Santa Clara*, No. 17-CV-
19 02115-LHK, 2018 WL 3777363, at *16 (N.D. Cal. Aug. 9, 2018) (citing *Kennedy* and
20 finding that deposition testimony did not create a triable issue where it flatly contradicted
21 prior statements and other evidence); *Watkins v. City of San Jose*, No. 15-CV-05786-
22 LHK, 2017 WL 1739159, at *13 (N.D. Cal. May 4, 2017) (same); *Lansmont Corp. v.*
23 *SPX Corp.*, No. 5:10-CV-05860 EJD, 2012 WL 6096674, at *4 (N.D. Cal. Dec. 7, 2012)
24 (“To the extent [the] deposition testimony is internally inconsistent, it does not itself
25 create a dispute of material fact because the former statement is rejected as self-serving,
26 vague and contrary to the remaining evidence.”).

27 Even if the Court were to credit these closing questions in Plaintiff’s deposition,
28 they say only that Plaintiff did not know her pain was caused by the filter until after the

1 unsuccessful removal procedure on April 7, 2011. But that knowledge is not required to
2 satisfy the discovery rule and trigger the statute of limitations period under Nebraska law.
3 “Discovery refers to the fact that one knows of the existence of an injury . . . and not that
4 one knows who or what may have caused that injury[.]” *Thomas*, 524 N.W.2d at 313.
5 “It is not necessary that a plaintiff have knowledge of the exact nature or source of the
6 problem, but only that a problem existed.” *Reinke Mfg. Co. v. Hayes*, 590 N.W.2d 380,
7 390 (Neb. 1999); see *Lindsay Mfg. Co. v. Universal Sur. Co.*, 519 N.W.2d 530, 504-05
8 (Neb. 1994). Thus, even if Plaintiff did not suspect that her abdominal pain was filter-
9 related, summary judgment would be warranted because there is no dispute that she knew
10 of her abdominal pain more than four years before she filed suit. See *Gordon*, 545
11 N.W.2d at 726.

12 Plaintiff presents a declaration in which she asserts that she had no reason to know
13 that the G2 filter had caused any injury until Dr. Smith attempted to remove the device.
14 Doc. 7959-1 at 31. This assertion does not help Plaintiff for the same reason – she did
15 not need to know the cause of her pain for the limitations period to be triggered.

16 Similarly, it is immaterial whether Plaintiff knew before the removal procedure
17 that the G2 filter had tilted, migrated, perforated her IVC, and fractured. Docs. 7959-1
18 at 31, 8009 at 7. A plaintiff “need not know the full extent of [her] damages before the
19 limitations period begins to run[.]” *Gordon*, 545 N.W.2d at 726. Regardless of when
20 Plaintiff became aware that the G2 filter had failed, she “discovered facts sufficient to put
21 [her] on notice of [the] injury well with the statutory period of limitations.” *Reinke*, 590
22 N.W.2d at 390.

23 Plaintiff’s declaration contains other assertions the Court must address. She does
24 not dispute in her declaration that she and Eggers discussed her abdominal pain, her IVC
25 filter, and the filter’s removal before March 14, 2011. Doc. 7959-1 at 30-31. But she
26 states, nonetheless, that the reason she scheduled the removal procedure “was not because
27 [she] knew that or believed at that time that the filter was causing any pain, but simply
28 because it had been brought to her attention that the filter was no longer needed and it

1 was a convenient time for [her] to have the procedure.” *Id.* She similarly states that she
2 met with Eggers for the pre-op exam “only because [she] thought the filter was no longer
3 needed and because April 2011 was a convenient time for [her] to have the procedure.”
4 *Id.* at 31. These statements are wholly inconsistent with Plaintiff’s deposition testimony
5 that she had conversations with Eggers about the G2 filter causing her abdominal pain
6 and, as a result of the conversation, made an appointment to have the filter removed.
7 Doc. 7350-2 at 13-15, 19.

8 “The general rule in the Ninth Circuit is that a party cannot create an issue of fact
9 by an affidavit contradicting [her] prior deposition testimony.” *Kennedy v. Allied Mut.*
10 *Ins. Co.*, 952 F.2d 262, 266 (9th Cir. 1991) (citations omitted). “This sham affidavit rule
11 prevents a party who has been examined at length on deposition from raising an issue of
12 fact simply by submitting an affidavit contradicting [her] own prior testimony, which
13 would greatly diminish the utility of summary judgment as a procedure for screening out
14 sham issues of fact.” *Yeager v. Bowlin*, 693 F.3d 1076, 1080 (9th Cir. 2012) (quoting
15 *Kennedy*, 952 F.2d at 266); *see Van Asdale v. Int’l Game Tech.*, 577 F.3d 989, 998 (9th
16 Cir. 2009) (explaining that the sham affidavit rule is necessary to maintain the principle
17 that the summary judgment procedure is an integral part of the federal rules). Because a
18 court is not to weigh conflicting evidence or make credibility determinations on summary
19 judgment, however, the sham affidavit rule “should be applied with caution.” *Van*
20 *Asdale*, 577 F.3d at 998 (citation omitted).

21 As noted above, certain statements in Plaintiff’s declaration flatly contradict her
22 prior deposition testimony. There is “clear and unambiguous” inconsistency, *Yeager*, 693
23 F.3d at 1080, between Plaintiff’s deposition testimony and the conclusory assertion in her
24 declaration that “[t]he first time [she] knew or had a reasonable basis for knowing that the
25 Bard G2 filter . . . had caused any injury was after Dr. Smith attempted to remove the
26 filter on April 7, 2011.” Doc. 7959-1 at 31. This is not a case of “newly-remembered
27 facts, or new facts, accompanied by a reasonable explanation[.]” *Yeager*, 693 F.3d
28 at 1081. Nor can the declaration be construed as simply “clarifying prior testimony

1 elicited by opposing counsel on deposition and minor inconsistencies that result from an
2 honest discrepancy[.]” *Van Asdale*, 577 F.3d at 999. Plaintiff affirmatively testified
3 during her deposition that she talked to Eggers about the G2 filter causing her pain.
4 Doc. 7350-4 at 13-15, 19. This testimony renders implausible Plaintiff’s subsequent
5 declaration that she had no reason to suspect that the G2 filter was the cause of her pain
6 and scheduled the removal procedure only because the filter was no longer needed and it
7 was a convenient time for the procedure. Doc. 7350 at 30-31. The Court therefore will
8 disregard the declaration in this respect. *See Yeager*, 693 F.3d at 1081; *Welsh v. Trimac*
9 *Transp. Servs. (W.) Inc.*, No. CV-11-01625-PHX-ROS, 2014 WL 12617737, at *4 (D.
10 Ariz. Mar. 31, 2014) (finding statements in a summary judgment affidavit to be a sham
11 where the plaintiff offered no explanation as to why he stated to the contrary in his
12 deposition testimony); *see also Momsen v. Neb. Methodist Hosp.*, 313 N.W.2d 208, 213
13 (Neb. 1981) (“Where a party without reasonable explanation testifies to facts materially
14 different concerning a vital issue, the change clearly being made to meet the exigencies
15 of pending litigation, such evidence is discredited as a matter of law and should be
16 disregarded.” (citations omitted)).

17 Plaintiff argues that Defendants’ own expert in interventional radiology has opined
18 that Plaintiff’s other health problems could have been a cause of her pain. Doc. 8009
19 at 7. But that opinion does not change the fact that Plaintiff herself felt pain she had not
20 experienced before the filter was implanted, and discovery under Nebraska law “refers to
21 the fact that one knows of the existence of an injury . . . and not that one knows who or
22 what may have caused that injury[.]” *Thomas*, 524 N.W.2d at 313. Nor does it change
23 the fact that Plaintiff called the IVC legal number for people with filter problems, talked
24 to Eggers about the pain she was experiencing and her suspicion that it was caused by the
25 filter, scheduled to have the filter removed, and had a pre-op meeting with Eggers that
26 resulted in a progress note stating that Plaintiff’s filter “has been causing her pain for the
27 last 3-4 months.” Doc. 7350-2 at 13.

28 Finally, Plaintiff asserts that the statute of limitations defense should be

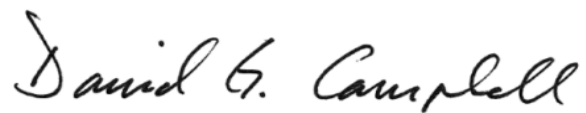
disregarded because this is a bellwether case. But the Court cannot conclude that legal defenses available under Nebraska law, and that would apply if this case were tried in Nebraska federal court, are somehow inapplicable because this is a bellwether trial. The Court is to apply the law of the transferee district when deciding cases in this MDL proceeding. *See In re Zicam Cold Remedy Mktg., Sales Practices, & Prods. Liab. Litig.*, 797 F. Supp. 2d. 940, 941 (D. Ariz. 2011) (citing *Ferens v. John Deere Co.*, 494 U.S. 516, 525 (1990)).⁴

IT IS ORDERED:

1. The following claims are **dismissed** based on Plaintiff's withdrawal of the claims before Defendants moved for summary judgment: manufacturing defect (Counts I and V), breach of warranty (Counts X and XI), loss of consortium, wrongful death, and survival (Counts XV-XVII).

2. Defendants' motion for summary judgment (Doc. 7341) is **granted** on the remaining claims: failure to warn (Counts II and VII), design defect (Counts III and IV), failure to recall (Count VI), misrepresentation (Counts VIII and XII), negligence per se (Count IX), concealment (Count XIII), consumer fraud and unfair trade practices (Count XIV), and punitive damages.

Dated this 17th day of August, 2018.



David G. Campbell
Senior United States District Judge

⁴ Plaintiff asserts that Defendants have not moved for summary judgment on the design defect claims (Counts III and IV). Doc. 8009 at 2. Defendants admit that they inadvertently omitted these counts from the introduction section of their motion, but note that the motion otherwise makes clear that, with respect to the statute of limitations argument, Defendants seek summary judgment as to all of Plaintiff's claims. Plaintiff had a full and fair opportunity to respond to that argument. The Court finds that the Nebraska statute of limitations for product liability cases applies to all of Plaintiff's claims. Given this ruling, the Court need not address Defendants' other summary judgment arguments.

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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**
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9 IN RE: Bard IVC Filters Products Liability
10 Litigation,

No. MDL 15-02641-PHX-DGC

11 _____
12 Lisa Hyde and Mark E. Hyde, a married
couple,

No. CV-16-00893-PHX-DGC

13 Plaintiffs,

ORDER

14 v.

15 C. R. Bard, Inc., a New Jersey corporation;
16 and Bard Peripheral Vascular, Inc., an
Arizona corporation,

17 Defendants.
18
19

20 The case brought by Plaintiffs Lisa and Mark Hyde is set for a bellwether jury trial
21 on September 18, 2018. During the final pretrial conference held on September 6, 2018,
22 it became clear that the parties disagree on whether Plaintiffs' negligence per se claim is
23 impliedly preempted under 21 U.S.C. § 337(a). The issue was raised and briefed by the
24 parties in their proposed final pretrial order and jury instructions. Docs. 12388 at 8-12,
25 12438 at 54-61. The Court asked the parties during the pretrial conference whether they
26 required further briefing and whether they wished to have this issue resolved before trial.
27 Counsel for both sides stated that no further briefing was needed and that a ruling before
28 trial would be helpful.

1 For the reasons stated below, the Court finds that the negligence per se claim is
2 preempted. This conclusion is purely legal – it is not affected by the evidence that would
3 be presented at trial. As a result, the Court concludes that it should enter judgment on
4 this claim before trial under Rule 56 of the Federal Rules of Civil Procedure. Although
5 decisions under that rule normally are made in response to a formal motion for summary
6 judgment, the rule makes clear that the Court may enter summary judgment *sua sponte*,
7 provided the parties are notified of the Court’s intention to make a dispositive decision
8 and have an opportunity to respond. *See* Fed. R. Civ. P. 56(f); *see also Celotex Corp. v.*
9 *Catrett*, 477 U.S. 317, 326 (1986) (“district courts are widely acknowledged to possess
10 the power to enter summary judgments *sua sponte*, so long as the losing party was on
11 notice that she had to come forward with all of her evidence”). In this instance, the
12 question is purely one of law, the parties have been fully heard, and the parties seek a
13 decision before trial. Such a decision will enable the parties to allocate their time and
14 evidence to the issues to be considered by the jury.¹

15 **I. Background.**

16 Plaintiff Lisa Hyde received a Bard IVC filter implant in 2011. In 2014, she
17 learned that the filter had tilted, perforated the IVC wall, and fractured. The filter and
18 fractured limbs were removed three months later.

19 Mrs. Hyde and her husband assert various claims. Doc. 364; Doc. 1, Case No.
20 CV-16-00893. Applying Wisconsin law, the Court granted summary judgment to
21 Defendants on several claims. Doc. 12007. Plaintiffs continue to assert claims for strict
22 liability design defect (Count III), negligent design (Count IV), negligence per se
23 (Count IX), loss of consortium (Count XV), and punitive damages. *Id.* at 19.²

24
25 ¹ Another approach would be to treat this issue as a motion by Defendants for
26 judgment as a matter of law under Rule 50. Although the standard for deciding such a
27 motion is the same as the standard under Rule 56, the Ninth Circuit has held that a
Rule 50 motion cannot be made before trial. *See McSherry v. City of Long Beach*, 423
F.3d 1015, 1019-22 (9th Cir. 2005). The Court accordingly will enter judgment under
Rule 56.

28 ² Defendants have explained that they did not seek summary judgment on the
negligence per se claim because they did not know the basis for the claim until the parties

1 **II. Discussion.**

2 Under Wisconsin law, negligence per se is a form of negligence that results from
3 violation of a statute. *See Friederichs v. Huebner*, 329 N.W.2d 890, 917 (Wis. 1983).
4 For the violation of a safety statute to constitute negligence per se, the plaintiff “must
5 show: (1) the harm inflicted was the type the statute was designed to prevent; (2) the
6 person injured was within the class of persons sought to be protected; and (3) there is
7 some expression of legislative intent that the statute become a basis for the imposition of
8 civil liability.” *Tatur v. Solsrud*, 498 N.W.2d 232, 235 (D. Wis. 1993) (citing *Walker v.*
9 *Bignell*, 301 N.W.2d 447, 454 (Wis. 1981)).

10 Plaintiffs do not allege violation of a Wisconsin statute as part of their negligence
11 per se claim. Rather, they contend that Defendants violated various provisions of the
12 Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, and related federal
13 regulations, in designing the Bard filter. Docs. 12388 at 8-9 (final pretrial order), 12400
14 at 4-7 (trial brief), 12438 at 54-59 (proposed jury instructions). Specifically, Plaintiffs
15 allege violations of 21 U.S.C. §§ 321, 331, and 352, and 21 C.F.R. §§ 803, 806.1,
16 820.100, 820.198, and 820.250. *Id.*; *see* Doc. 364 ¶ 231.

17 As noted above, the third element of Wisconsin’s negligence per se claim requires
18 “some expression of legislative intent that the statute become a basis for the imposition of
19 civil liability.” *Tatur*, 498 N.W.2d at 235. As other courts have recognized, however,
20 “[f]ar from containing an expression that FDA regulations are intended to form the basis
21 for civil liability, the [FDCA] expresses the opposite intention.” *Cali v. Danek Med.,*
22 *Inc.*, 24 F. Supp. 2d 941, 954 (W.D. Wis. 1998). Under § 337(a), “[v]iolations of the
23 FDA are enforceable only by the United States.” *Id.* “The FDCA leaves no doubt that it
24 is the Federal Government rather than private litigants who are authorized to file suit for
25 noncompliance with the medical device provisions.” *Buckman Co. v. Plaintiffs’ Legal*
26 *Comm.*, 531 U.S. 341, 349 n.4 (2001). Thus, “a private litigant cannot bring a state-law
27 claim against a defendant when the state-law claim is in substance (even if not in form) a

28

prepared the proposed final pretrial order.

1 claim for violating the FDCA – that is, when the state claim would not exist if the FDCA
2 did not exist.” *Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 WL 3652311,
3 at *7 (N.D. Ga. Aug. 19, 2011) (citation omitted); *see Ellis v. C. R. Bard, Inc.*, 311 F.3d
4 1272, 1284 n.10 (11th Cir. 2002) (noting that under § 337(a) “no private right of action
5 exists for a violation of the FDCA”).

6 In *Buckman*, the Supreme Court held that a state law claim that a defendant made
7 fraudulent statements to the FDA, in violation of the FDCA, was impliedly preempted
8 by § 337(a) because the claim “exist[ed] solely by virtue” of FDCA requirements and
9 therefore “would not be relying on traditional state tort law which had predated the
10 [FDCA].” 531 U.S. at 353. The same is true here. Plaintiffs’ “claim of negligence per
11 se would not exist prior to the enactment of the FDCA . . . because the claim only alleges
12 violation of that law.” *Leonard*, 2011 WL 3652311, at *8. As in *Buckman*, Plaintiffs’
13 “negligence per se claim (or, more appropriately characterized, [their] negligence claim
14 based solely on violations of . . . FDA regulations) is impliedly preempted by the
15 FDCA.” *Grant v. Corin Grp. PLC*, No. 3:15-CV-169-CAB-BLM, 2016 WL 4447523,
16 at *4 (S.D. Cal. Jan. 15, 2016); *see Connelly v. St. Jude Med., Inc.*, No. 5:17-cv-02005-
17 EJD, 2017 WL 3619612, at *5 (N.D. Cal. Aug. 23, 2017) (negligence per se claim
18 preempted where it was “based entirely on violations of the FDCA and its implementing
19 regulations”); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 862 (W.D. Tenn. 2015) (“If
20 Plaintiffs claim negligence based solely on Defendants’ failure to comply with federal
21 law or solely on illegal off-label promotion (i.e. negligence per se), Plaintiffs’ claims are
22 impliedly preempted under *Buckman*.”); *Dunbar v. Medtronic, Inc.*, No. CV 14-01529-
23 RGK AJWX, 2014 WL 3056026, at *6 (C.D. Cal. June 25, 2014) (“[A] negligence per se
24 claim alleging violation of the FDCA is nothing more than a private right of action under
25 the FDCA for damages. Since the latter is not available as a result of § 337(a), the Court
26 finds that the former is preempted as well.”); *McClelland v. Medtronic, Inc.*, 944 F. Supp.
27 2d 1193, 1200 (M.D. Fla. 2013) (“Plaintiff’s attempt to recast a claim for violation of the
28 FDCA as a state-law negligence claim is impliedly barred by § 337(a).”); *Franklin v.*

1 *Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *8 (D. Colo.
2 May 12, 2010) (“[T]o the extent that Plaintiff seeks to ground her negligence per se . . .
3 claim[] on allegations that Defendant violated the FDCA – namely, by selling a
4 misbranded and adulterated product – these claims are impliedly preempted pursuant
5 to 21 U.S.C. § 337(a).”); *Talley v. Danek Med., Inc.*, 7 F. Supp. 2d 725, 731 (E.D. Va.
6 1998) (“[T]he FDCA expressly prohibits the bringing of a private cause of action under
7 the Act. To allow a state negligence per se action based upon alleged violations of the
8 FDCA would defeat the purpose of that prohibition.”).

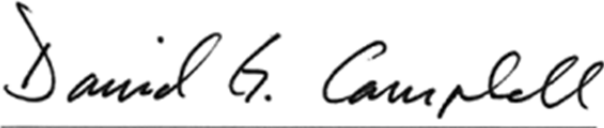
9 Plaintiffs’ citation of *Garross v. Medtronic, Inc.*, 77 F. Supp. 3d 809, 816 (E.D.
10 Wis. 2015), is not persuasive. Doc. 12388 at 9-10. The plaintiff in that case did not
11 bring a negligence per se claim, but instead asserted traditional common law torts such as
12 design defect, failure to warn, and negligence. *Garross*, 77 F. Supp. 3d at 813. Those
13 claims were not impliedly preempted under *Buckman* “because none of them [arose]
14 solely from a violation of federal law; rather, each [arose] from an independent, well-
15 recognized duty owed under state law.” *Id.* at 816; *see also Hoffmann v. Wis. Elec.*
16 *Power Co.*, 664 N.W.2d 55, 62 (Wis. 2003) (noting that “the enactment of safety statutes
17 . . . does not abolish the duty arising under common-law negligence”). In this case,
18 Plaintiffs retain and will assert at trial a common law negligent design claim; that claim is
19 not affected by this ruling.

20 Plaintiffs cite cases holding that violations of FDCA regulations may support
21 negligence per se claims in Wisconsin. Doc. 12388 at 9-10 (citing *Lukaszewicz v. Ortho*
22 *Pharm. Corp.*, 510 F. Supp. 961, 964 (E.D. Wis. 1981) (pre-*Buckman* decision holding
23 that violation of federal regulation for prescription drug labeling supported negligence
24 per se claim under Wisconsin law); *Marvin v. Zydus Pharms. (USA) Inc.*, 203 F. Supp. 3d
25 985, 992 (W.D. Wis. 2016) (finding that plaintiffs may bring a negligence per se claim
26 under Wisconsin law based on a violation of federal medication guide regulations);
27 Doc. 12400 at 13 (citing *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 874 (Wis. Ct.
28 App. 2004) (“In Wisconsin, violations of the FDA regulations may constitute negligence

1 per se.”)). But these cases are squarely at odds with § 337(a). The plain language of that
2 section and the *Buckman* decision indicate that such claims fail. See *Dunbar*, 2014 WL
3 3056026, at *6. Even if state law recognizes the claims, federal law preempts them. See
4 *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (finding state law claim
5 preempted where the plaintiff was not suing under state law for conduct that happens to
6 violate the FDCA, but instead is suing solely “because the conduct violates the FDCA.”)
7 (emphasis in original). This Court reached the same conclusion in previous bellwether
8 cases. See Docs. 8874 at 14-18, 10404 at 14-17 (finding negligence per se claims
9 impliedly preempted in the Booker and Jones bellwether cases).

10 **IT IS ORDERED** that judgment is entered in favor of Defendants on Plaintiffs’
11 negligence per se claim (Count IX).

12 Dated this 11th day of September, 2018.

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16 David G. Campbell
17 Senior United States District Judge
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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**
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9 IN RE: Bard IVC Filters Products Liability
10 Litigation,

No. MDL 15-02641-PHX-DGC

11 _____
12 Lisa Hyde and Mark E. Hyde, a married
couple,

No. CV-16-00893-PHX-DGC

13 Plaintiffs,

ORDER

14 v.

15 C. R. Bard, Inc., a New Jersey corporation;
16 and Bard Peripheral Vascular, Inc., an
Arizona corporation,

17 Defendants.
18
19

20 The case brought by Plaintiffs Lisa and Mark Hyde is set for a bellwether jury trial
21 on September 18, 2018. Defendants seek reconsideration of the Court's summary
22 judgment ruling that Wisconsin's product liability statute, Wis. Stat. § 895.047, does not
23 create a rebuttable presumption that the Bard IVC filter is not defective. Doc. 12007
24 at 10-12. The issue was addressed by the parties in their trial briefs and proposed jury
25 instructions, and discussed at the final pretrial conference held on September 6, 2018.
26 *See* Docs. 12358 at 11-14, 12438 at 49, 12400 at 11-12. Defendants stated in their trial
27 brief that the issue warrants more detailed briefing (Doc. 12358 at 13), but made clear at
28 the pretrial conference that the materials submitted are sufficient. For the reasons stated

1 below, the Court will deny Defendants’ request for reconsideration.

2 Section 895.047(3)(b) creates a rebuttable presumption that a product is not
3 defective if it complied with “relevant standards, conditions, or specifications adopted or
4 approved by a federal or state law or agency[.]” Defendants argued in their summary
5 judgment motion that the design of the Bard filter and the warnings provided with the
6 device are presumed to be non-defective because Bard complied with the FDA’s 510(k)
7 process. Doc. 7359 at 12. The Court rejected this argument because 510(k) review
8 focuses on equivalence, not safety. Doc. 12007 at 11. The Court noted that Defendants
9 had cited no legal authority for the proposition that the presumption applies even if the
10 government standard is not safety. *Id.* at 12 n.4.

11 Defendants’ recent briefing relies on *Kilty v. Weyerhaeuser Co.*, No. 16-CV-515-
12 WMC, 2018 WL 2464470 (W.D. Wis. June 1, 2018), a decision issued after summary
13 judgment briefing was complete. Defendants argue that it would be incorrect to conclude
14 that only safety regulations are entitled to the presumption of non-defectiveness under
15 § 895.047(3)(b), but *Kilty* did not consider this issue. The regulations in *Kilty* were safety
16 standards – regulations enacted by the National Institute of Occupational Safety and
17 Health and the U.S. Bureau of Mines concerning the performance and quality of
18 respiratory equipment used to protect workers against asbestos exposure. 2018 WL
19 2464470, at *3 (discussing regulations set forth in 30 C.F.R. 11 *et seq.*); *see also*
20 *Commercial Union Ins. Co. v. United States*, No. CIV.A. 87-3913, 1988 WL 92081, at *1
21 (E.D. La. Aug. 19, 1988) (explaining that “Title 30 of the Code of Federal Regulations
22 establishes a schedule for testing to insure compliance with safety standards”).

23 The fact that the safety standards in *Kilty* were sufficient to meet § 895.047(3)(b)’s
24 “relevant standards” requirement, Defendants contend, “does not mean that ‘safety’ is a
25 necessary condition under the statute.” Doc. 12358 at 12 n.17. But *Kilty* does not
26 address this issue one way or the other, and Defendants cite no authority holding that the
27 Wisconsin presumption arises from non-safety regulations. Surely the statute’s reference
28 to “*relevant* standards, conditions, or specifications” requires some connection to the

1 alleged defect. Wis. Stat. § 895.047(3)(b) (emphasis added). For example, it would
2 make no sense to hold that an auto manufacturer's compliance with federally-
3 promulgated fuel efficiency standards gives rise to a presumption of non-defectiveness in
4 a roll-over case where the plaintiff claims that the car's suspension was defective. *Kilty's*
5 reliance on federal regulations that clearly concerned the safety of respiratory equipment
6 does nothing to suggests that this Court erred when it held that Defendants' compliance
7 with the 510(k) process does give rise to the statutory presumption. As the Court noted
8 in its summary judgment ruling, other cases specifically have held that § 895.047(3)(b)
9 creates no rebuttable presumption for medical devices cleared under 510(k) review
10 because that review does not concern the safety of the product. *See Hall v. Boston Sci.*
11 *Corp.*, No. 2:12-CV-08186, 2015 WL 874888, at *2 (S.D. W. Va. Feb. 27, 2015)
12 ("510(k) is not a 'relevant standard' here. Section 895.047 concerns whether a defect
13 rendered the product 'unreasonably dangerous,' § 895.047(1), and, as the Supreme Court
14 has held, 510(k) compliance does not go to the safety of a product."); *Williams v. Boston*
15 *Sci. Corp.*, No. 2:12-CV-02052, 2016 WL 1448860, at *3 (S.D. W. Va. Apr. 12, 2016)
16 (same). The Court continues to find these cases persuasive.¹

17 Defendants argue that whether the presumption applies in this case, and whether
18 Plaintiffs have overcome it, are questions of fact for the jury to decide. Doc. 12358 at 13
19 n.18. Defendants cite language from the Wisconsin model jury instruction, Wis JI-Civil
20 § 3260.1, stating that the jury "must resolve this conflict." *Id.* But the "conflict" referred
21 to is not whether the rebuttable presumption has arisen, but whether it has been
22 overcome. *See* Doc. 12438 at 49 (quoting Wis JI-Civil § 3260.1 ("There was evidence
23 received that at the time of sale, the product complied in material respects with relevant
24 standards . . . adopted or approved by a federal or state law or agency. From this

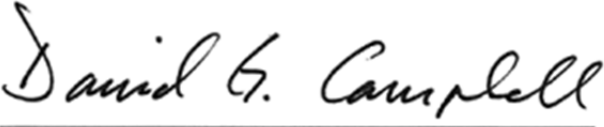
25
26 ¹ Defendants contend that it would be unfair for Plaintiffs to argue that Defendants
27 are liable for negligence per se based on violations of the "safety" standards set forth in
28 FDCA and its implementing regulations if Defendants are precluded from relying on the
same standards for purposes of § 895.047(3)(b). Doc. 12358 at 13. This issue is moot
because the Court has entered judgment in favor of Defendants on the negligence per se
claim. Doc. 12589.

1 evidence, a rebuttable presumption arises that the product was not defective. However,
2 there is also evidence which may be believed by you that the product is defective. You
3 must resolve this conflict.”)). Whether a defendant complied in material respects with
4 the government standard may also create a triable issue of fact. *See Merryfield v. KLI,*
5 *Inc.*, No. 17-C-742, 2018 WL 4178178, at *4 (E.D. Wis. Aug. 30, 2018) (denying
6 summary judgment in part because the jury reasonably could find that the product was
7 not made according to government specifications).

8 But whether the government standard is one from which a rebuttable presumption
9 may arise in the first instance – that is, whether it is a “relevant” standard for purposes of
10 § 895.047(3)(b) – is a question of law for the court. *See Williams*, 2016 WL 1448860,
11 at *3 (finding as a matter of law that § 895.047(3)(b) creates no presumption of non-
12 defectiveness for medical devices cleared under 510(k) review because that review does
13 not concern the safety of the product); *Kilty*, 2018 WL 2464470, at *3 (finding that the
14 presumption arose where the government issued specific safety regulations and certified
15 the manufacture’s compliance). Addressing that question of law, the Court again
16 concludes that the 510(k) process, which looked at substantial equivalence rather than
17 safety, and did not otherwise approve or certify the design of the Bard filter, is not a
18 relevant standard for purposes of the presumption in § 895.047(3)(b). The Court will not
19 instruct the jury that the presumption exists in this case.

20 **IT IS ORDERED** that Defendants’ request for reconsideration (Doc. 12358
21 at 11-14) is **denied**.

22 Dated this 13th day of September, 2018.

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26 David G. Campbell
27 Senior United States District Judge
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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products Liability
Litigation,

No. MDL 15-02641-PHX-DGC

**CASE MANAGEMENT ORDER
NO. 38**

Following the close of evidence in the Hyde case, the Court conferred with the parties regarding scheduling matters. On the basis of the conference, the Court enters the following order.

I. Future Bellwether Trials.

The Court confirmed that it will hold two more bellwether trials in this MDL proceeding – Plaintiffs Mulkey and Tinlin. The Court will not hold a sixth bellwether trial. Because discovery in the Tinlin case is still being completed and Ms. Mulkey's health appears at this time to permit a trial, the Court will hold the Mulkey trial in February and the Tinlin trial in May. In the meantime, the Tinlin discovery schedule set forth in Doc. 12061, as modified by Doc. 12759, shall remain in place. The Court will rule as promptly as possible on the motion for summary judgment in the Mulkey case. If the Court grants summary judgment in Mulkey, the Tinlin trial will be held in February. If Ms. Mulkey's health worsens, the Court will hear from the parties on whether the Tinlin trial should be moved to February, but this issue should be raised with the Court

1 during the week of November 12, 2018, in light of the jury questionnaire schedule set
2 forth below.

3 **II. February Bellwether Trial.**

4 **A. Jury Questionnaire and Jury Selection.**

5 1. By **November 26, 2018**, the parties shall provide the Court with
6 proposed changes to the questionnaire used in the Hyde bellwether trial. The Court will
7 consider these proposals in finalizing the questionnaire for the February trial.

8 2. The Clerk shall mail the questionnaire to 200 jurors no later than
9 **November 30, 2018**. The questionnaire will instruct the prospective jurors to return it to
10 the Court no later than **January 4, 2019**.

11 3. A thumb drive will be prepared for counsel (one for each side)
12 containing copies of the questionnaires and will be available for pickup at the jury office
13 on **January 11, 2019**. The thumb drive and any paper copies made by counsel must be
14 returned to the Court by counsel on the day of jury selection.

15 4. On **January 18, 2019**, the Court will provide the parties with a list
16 of prospective jurors the Court proposes to excuse for hardship on the basis of their
17 responses to the first question in the questionnaire.

18 5. The Court will hold a final pretrial conference case on
19 **January 28, 2019 at 10:00 a.m.** At the final pretrial conference, counsel will be
20 permitted to challenge the Court's excusal of any of the listed jurors for hardship. If
21 counsel do not object to the Court's proposed excusal of a particular juror for hardship,
22 that juror will be excused from further involvement in this case. After hearing counsel's
23 objections to hardship excusals, the Court will determine which of the challenged jurors
24 should be excused for hardship and which should appear for voir dire. In addition,
25 counsel shall be prepared to make challenges for cause to jurors on the basis of
26 information contained in their questionnaires. These challenges should be limited to
27 jurors who clearly could not serve as a fair juror on the basis of their questionnaire
28 answers. The Court will rule on these challenges at the final pretrial conference. All

1 prospective jurors who returned questionnaires and who have not been excused for
2 hardship or successfully challenged for cause will be candidates for voir dire.

3 6. On **February 11, 2019, at 9:00 a.m.**, 50 prospective jurors will be
4 called to Court to appear for voir dire. The Court will permit counsel to ask follow-up
5 questions of individual jurors based on information contained in the juror questionnaires.
6 Counsel should not venture into new subjects – they should limit their follow-up
7 questions to the items covered in the questionnaire. Following voir dire, the Court will
8 hear and rule on challenges for cause.

9 7. The Court will seat 9 jurors. Each side will have 3 pre-emptory
10 strikes.

11 8. The Court anticipates that opening statements and evidence trial will
12 begin on the afternoon of **February 11, 2019**.

13 **B. Dispositive and *Daubert* Motions.**

14 Dispositive and *Daubert* motions in the Tinlin case shall be filed by
15 **December 7, 2018**, responses by **December 21, 2018**, and replies by **December 28,**
16 **2019**. See Doc. 12061 ¶ 7.

17 **C. Motions in Limine.**

18 Motions in limine, limited to three pages each, shall be filed by
19 **December 14, 2018**. Responses to motions in limine, limited to three pages each, shall
20 be filed by **December 28, 2019**. No replies shall be filed.

21 **D. Deposition Designations.**

22 The parties shall provide deposition designations by **December 14, 2019**.

23 **E. Final Pretrial Order.**

24 The proposed final pretrial order shall be submitted by **January 11, 2019**. The
25 Court will enter a separate order governing the materials that should be submitted with
26 the final pretrial order.

27 **F. Final Pretrial Conference.**

28 The Court will hold a final pretrial conference on **January 28, 2019 at 10:00 a.m.**

1 **G. Trial Days.**

2 Trial in will be held on **February 11-15, 19-22, 25-28**, and **March 1, 2019**.
3 Plaintiff will be allotted 33 hours of trial time and Defendants will be allotted 30 hours of
4 trial time. This schedule should allow the case to get to the jury by the morning of
5 February 28, 2019.

6 **III. May Bellwether Trial.**

7 **A. Jury Questionnaire and Jury Selection.**

8 1. By **March 1, 2019**, the parties shall provide the Court with proposed
9 changes to the questionnaire. The Court will consider these proposals in finalizing the
10 questionnaire.

11 2. The Clerk shall mail the questionnaire to 200 jurors no later than
12 **March 8, 2019**. The questionnaire will instruct the prospective jurors to return it to the
13 Court no later than **April 5, 2019**.

14 3. A thumb drive will be prepared for counsel (one for each side)
15 containing copies of the questionnaires and will be available for pickup at the jury office
16 on **April 12, 2019**. The thumb drive and any paper copies made by counsel must be
17 returned to the Court by counsel on the day of jury selection.

18 4. On **April 19, 2019**, the Court will provide the parties with a list of
19 prospective jurors the Court proposes to excuse for hardship on the basis of their
20 responses to the first question in the questionnaire.

21 5. The Court will hold a final pretrial conference case on
22 **April 30, 2019 at 10:00 a.m.** At the final pretrial conference, counsel will be permitted
23 to challenge the Court's excusal of any of the listed jurors for hardship. If counsel do not
24 object to the Court's proposed excusal of a particular juror for hardship, that juror will be
25 excused from further involvement in this case. After hearing counsel's objections to
26 hardship excusals, the Court will determine which of the challenged jurors should be
27 excused for hardship and which should appear for voir dire. In addition, counsel shall be
28 prepared to make challenges for cause to jurors on the basis of information contained in

1 their questionnaires. These challenges should be limited to jurors who clearly could not
2 serve as a fair juror on the basis of their questionnaire answers. The Court will rule on
3 these challenges at the final pretrial conference. All prospective jurors who returned
4 questionnaires and who have not been excused for hardship or successfully challenged
5 for cause will be candidates for voir dire.

6 6. On **May 13, 2019, at 9:00 a.m.**, 50 prospective jurors will be called
7 to Court to appear for voir dire. The Court will permit counsel to ask follow-up questions
8 of individual jurors based on information contained in the juror questionnaires. Counsel
9 should not venture into new subjects – they should limit their follow-up questions to the
10 items covered in the questionnaire. Following voir dire, the Court will hear and rule on
11 challenges for cause.

12 7. The Court will seat 9 jurors. Each side will have 3 pre-emptory
13 strikes.

14 8. The Court anticipates that opening statements and evidence will
15 begin on the afternoon of **May 13, 2019**.

16 **B. Dispositive and *Daubert* Motions.**

17 Dispositive and *Daubert* motions shall be filed by **February 1, 2019**, responses by
18 **March 1, 2019**, and replies by **March 15, 2019**.

19 **C. Motions in Limine.**

20 Motions in limine, limited to three pages each, shall be filed by **March 29, 2018**.
21 Responses to motions in limine, limited to three pages each, shall be filed by
22 **April 12, 2019**. No replies shall be filed.

23 **D. Deposition Designations.**

24 The parties shall provide deposition designations by **March 29, 2019**.

25 **E. Final Pretrial Order.**

26 The proposed final pretrial order shall be submitted by **April 12, 2019**. The Court
27 will enter a separate order governing the materials that should be submitted with the final
28 pretrial order.

The Court will hold a final pretrial conference on **April 30, 2019 at 10:00 a.m.**

Trial will be held on **May 13-17, 20-24, and 28-31**. Plaintiff will be allotted 33 hours of trial time and Defendants will be allotted 30 hours of trial time. This schedule should allow the case to get to the jury by the morning of May 30, 2019.

Defendants shall file any motion to seal trial exhibits in the Jones and Hyde cases by **October 26, 2018**.

Counsel shall meet in person and engage in good faith global settlement talks no later than **November 30, 2018**. Within five working days after the talks, the parties shall file a joint report informing the Court that good faith settlement talks have been held and reporting generally on the outcome of such talks.

The Court intends to remand all cases in this MDL shortly after completion of the May 2019 bellwether trial.

Defendants shall, by **November 2, 2018**, file a motion with the panel on multidistrict litigation to expand this MDL to include the SNF cases or to create a new MDL including the SNF cases. If the panel concludes that the motion should be granted in some respect, the undersigned judge will be willing to oversee the SNF cases.

Dated this 5th day of October, 2018.

David G. Campbell

David G. Campbell
United States District Judge

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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**

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9 IN RE: Bard IVC Filters Products Liability
10 Litigation,

No. MDL 15-02641-PHX-DGC

11 **CASE MANAGEMENT ORDER NO. 39**
12 **(Tinlin Bellwether Case)**
13
14

15 In Case Management Order (“CMO”) No. 36, issued August 2, 2018, the Court set
16 a schedule for the parties to follow in preparing the Tinlin bellwether case for trial.
17 Doc. 12061. Certain of those deadlines were extended two months later. Doc. 12759.
18 In CMO No. 38, the Court set a schedule for the final two bellwether trials, Mulkey and
19 Tinlin, to be held in February and May 2019. Doc. 12853 at 2-6. The Court determined
20 that Mulkey should be tried in February unless the Court were to grant summary
21 judgment in the case or Ms. Mulkey’s health were to worsen. *Id.* at 1-2. The Court left
22 open the possibility that Tinlin could be tried in February instead of May. *Id.*

23 The parties have now filed a stipulation that Tinlin should be tried only in the May
24 bellwether slot given that the present schedule for completion of discovery in Tinlin is
25 not feasible. Docs. 12895, 12924. The parties propose an amended discovery schedule
26 for Tinlin. *Id.*

27 The Court will accept the parties’ stipulation that Tinlin should be tried in May
28 and approve the proposed changes to the discovery schedule. This order will control the

1 schedule for the Tinlin trial. The deadlines and dates for the February bellwether trial, as
2 set forth in CMO 38, will continue to apply to Mulkey. *See* Doc. 12538 at 2-4.

3 **I. Tinlin Discovery Schedule.**

4 The parties shall follow this amended schedule in preparing the Tinlin case for
5 trial in May 2019:

6 1. The parties shall obtain updated medical records by
7 **November 12, 2018.**

8 2. The parties shall complete the depositions of treating physicians and
9 fact witnesses by **December 10, 2018.**

10 3. Plaintiff's case-specific expert disclosures shall be completed by
11 **November 16, 2018**

12 4. Defendants' case-specific expert disclosures shall be completed by
13 **December 17, 2018.**

14 5. Case-specific experts shall be deposed by **January 18, 2019.**

15 **II. Tinlin Trial Schedule.**

16 **A. Jury Questionnaire and Jury Selection.**

17 1. By **March 1, 2019**, the parties shall provide the Court with proposed
18 changes to the questionnaire. The Court will consider these proposals in finalizing the
19 questionnaire.

20 2. The Clerk shall mail the questionnaire to 200 jurors no later than
21 **March 8, 2019.** The questionnaire will instruct the prospective jurors to return it to the
22 Court no later than **April 5, 2019.**

23 3. A thumb drive will be prepared for counsel (one for each side)
24 containing copies of the questionnaires and will be available for pickup at the jury office
25 on **April 12, 2019.** The thumb drive and any paper copies made by counsel must be
26 returned to the Court by counsel on the day of jury selection.

27 4. On **April 19, 2019**, the Court will provide the parties with a list of
28 prospective jurors the Court proposes to excuse for hardship on the basis of their

1 responses to the first question in the questionnaire.

2 5. The Court will hold a final pretrial conference on **April 30, 2019**
3 **at 10:00 a.m.** At the final pretrial conference, counsel will be permitted to challenge the
4 Court's excusal of any of the listed jurors for hardship. If counsel do not object to the
5 Court's proposed excusal of a particular juror for hardship, that juror will be excused
6 from further involvement in this case. After hearing counsel's objections to hardship
7 excusals, the Court will determine which of the challenged jurors should be excused for
8 hardship and which should appear for voir dire. In addition, counsel shall be prepared to
9 make challenges for cause to jurors on the basis of information contained in their
10 questionnaires. These challenges should be limited to jurors who clearly could not serve
11 as a fair juror on the basis of their questionnaire answers. The Court will rule on these
12 challenges at the final pretrial conference. All prospective jurors who returned
13 questionnaires and who have not been excused for hardship or successfully challenged
14 for cause will be candidates for voir dire.

15 6. On **May 13, 2019, at 9:00 a.m.**, 50 prospective jurors will be called
16 to Court to appear for voir dire. The Court will permit counsel to ask follow-up questions
17 of individual jurors based on information contained in the juror questionnaires. Counsel
18 should not venture into new subjects – they should limit their follow-up questions to the
19 items covered in the questionnaire. Following voir dire, the Court will hear and rule on
20 challenges for cause.

21 7. The Court will seat 9 jurors. Each side will have 3 pre-emptory
22 strikes.

23 8. The Court anticipates that opening statements and evidence will
24 begin on the afternoon of **May 13, 2019**.

25 **B. Dispositive and *Daubert* Motions.**

26 Dispositive and *Daubert* motions shall be filed by **February 1, 2019**, responses by
27 **March 1, 2019**, and replies by **March 15, 2019**.

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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**
8

9 IN RE: Bard IVC Filters Products Liability
10 Litigation,
11 _____

No. MDL15-2641-PHX-DGC

12 Debra and James Tinlin, a married couple,
13 Plaintiffs,

No. CV16-0263-PHX-DGC

14 v.

ORDER

15 C. R. Bard, Inc., a New Jersey corporation;
16 and Bard Peripheral Vascular, Inc., an
17 Arizona corporation,
18 Defendants.

19 This multidistrict litigation proceeding (“MDL”) involves thousands of personal
20 injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular,
21 Inc. (collectively, “Bard”). Bard manufactures and markets medical devices, including
22 inferior vena cava (“IVC”) filters. The MDL Plaintiffs received implants of Bard IVC
23 filters and claim they are defective and have caused serious injury or death.

24 One of the MDL cases is brought by Plaintiff Debra Tinlin. She received a Bard
25 filter fourteen years ago. Her case has been chosen as one of several bellwether cases
26 and is set for trial in May 2019. Defendants have filed a motion for summary judgment.
27 Doc. 15071. The motion is fully briefed. Docs. 15696, 16011. The parties request oral
28 argument, but it will not aid the Court’s decision. *See* Fed. R. Civ. P. 78(b); LRCiv

1 7.2(f). For reasons stated below, the Court will grant the motion in part and deny it
2 in part.

3 **I. Background.**

4 The IVC is a large vein that returns blood to the heart from the lower body. An
5 IVC filter is a device implanted in the IVC to catch blood clots before they reach the
6 heart and lungs. This MDL involves multiple versions of Bard IVC filters – the
7 Recovery, G2, G2X, Eclipse, Meridian, and Denali. They are spider-shaped devices that
8 have multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with
9 elastic hooks that attach to the IVC wall, and bent arms to catch or break up blood clots.

10 The MDL Plaintiffs allege that Bard filters are more dangerous than other IVC
11 filters because they have higher risks of tilting, perforating the IVC, or fracturing
12 and migrating to vital organs. Plaintiffs further allege that Bard failed to warn patients
13 and physicians about these higher risks. Defendants dispute these allegations, contending
14 that Bard filters are safe and effective, that their complication rates are low and
15 comparable to those of other IVC filters, and that the medical community is aware of the
16 risks associated with IVC filters.

17 **II. The Tinlin Plaintiffs.**

18 Plaintiff Debra Tinlin has a history of deep vein thrombosis and pulmonary
19 emboli. She received a Bard Recovery filter on May 7, 2005. Dr. Joshua Riebe
20 implanted the filter.

21 On June 10, 2013, Ms. Tinlin experienced cardiac tamponade after the filter
22 fractured and two struts embolized in the right ventricle of her heart. She had emergency
23 surgery to drain a pericardial effusion. No fractured strut was found during the
24 procedure. She was discharged ten days later.

25 On July 31, 2013, a fractured strut was removed through open heart surgery. A
26 chest scan showed several other struts perforating the IVC wall. Subsequent scans
27 revealed multiple fractured struts in the pulmonary arteries. These struts and the filter
28 have not been removed.

1 Ms. Tinlin and her husband assert various claims against Bard under Wisconsin
2 law, some of which have been withdrawn.¹ The following claims remain: failure to warn
3 (Counts II and VII), design defect (Counts III and IV), misrepresentation (Counts VIII
4 and XII), concealment (Count XIII), deceptive trade practices (Count XIV), and loss of
5 consortium (Count XV). *See* Doc. 364 (master complaint); Doc. 1, Case No. CV-16-
6 00263 (short-form complaint).²

7 Defendants seek summary judgment on the remaining claims and future damages,
8 but not on Plaintiff's request for punitive damages. Doc. 15071 at 2-4. The Court will
9 grant summary judgment on the misrepresentation and deceptive trade practices claims,
10 deny summary judgment on the claims for failure to warn, design defect, concealment,
11 and loss of consortium, and grant summary judgment in part with respect to future
12 damages.

13 **III. Summary Judgment Standard.**

14 A party seeking summary judgment "bears the initial responsibility of informing
15 the court of the basis for its motion and identifying those portions of [the record] which it
16 believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v.*
17 *Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is warranted where the moving
18 party "shows that there is no genuine dispute as to any material fact and the movant is
19 entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Summary judgment is
20 also appropriate against a party who "fails to make a showing sufficient to establish the
21 existence of an element essential to that party's case, and on which that party will bear
22 the burden of proof at trial." *Celotex*, 477 U.S. at 322.

23
24 ¹ The parties agree that Wisconsin law governs the Tinslins' claims. Doc. 15071
at 3 n.1.

25 ² The master complaint is the operative pleading in this MDL. It gives notice,
26 pursuant to Rule 8, of the allegations that Plaintiffs assert generally. Plaintiff-specific
27 allegations are contained in individual short-form complaints and fact sheets. *See*
28 Doc. 249 at 6. The master complaint asserts seventeen claims and seeks both
compensatory and punitive damages. Doc. 364 ¶¶ 166-349. The Tinslins do not assert
wrongful death or survival claims (Counts XVI and XVII), and have withdrawn claims
for manufacturing defect (Counts I and V), failure to recall (Count VI), negligence per se
(Count IX), and breach of warranty (Counts X and XI). *See* Doc. 15071 at 2.

1 Only disputes over facts that might affect the outcome of the suit will preclude
2 summary judgment, and the disputed evidence must be “such that a reasonable jury could
3 return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S.
4 242, 248 (1986). The evidence must be viewed in the light most favorable to the
5 nonmoving party, and all justifiable inferences are drawn in that party’s favor because
6 “[c]redibility determinations, the weighing of evidence, and the drawing of inferences
7 from the facts are jury functions[.]” *Id.* at 255; *see Matsushita Elec. Indus. Co. v. Zenith*
8 *Radio Corp.*, 475 U.S. 574, 587 (1986)

9 **III. Failure to Warn Claims (Counts II and VII).**

10 Plaintiffs assert strict liability and negligent failure to warn claims. *See* Doc. 364
11 ¶¶ 171-81, 210-17; Doc. 1 at 3, Case No. CV-16-00263. To establish each claim,
12 Plaintiffs must show, among other things, that the lack of an adequate warning was a
13 cause of their injuries. *See* Wis. Stat. § 895.047(1)(e) (a plaintiff asserting a strict
14 liability claim must prove that “the defective condition was a cause” of her injuries);
15 *Kessel v. Stansfield Vending, Inc.*, 714 N.W.2d 206, 211 (Wis. Ct. App. 2006) (a plaintiff
16 claiming negligent failure to warn must prove a “causal connection between the
17 defendant’s breach of the duty of care and the plaintiff’s injury”). “Under Wisconsin
18 law, negligence or defect ‘caused’ an injury if it was a substantial factor in producing the
19 injury.” *Burton v. Am. Cyanamid*, No. 07-CV-0303, 2019 WL 325318, at *2 (E.D. Wis.
20 Jan. 25, 2019); *see Sumnicht v. Toyota Motor Sales, U.S.A.*, 360 N.W.2d 2, 11 (Wis.
21 1984) (“The long-standing test for cause in Wisconsin is whether the defect was a
22 substantial factor in producing the injury.”); *Morgan v. Pa. Gen. Ins.*, 275 N.W.2d 660,
23 666 (Wis. 1979) (“The test of cause-in-fact is whether the negligence was a ‘substantial
24 factor’ in producing the injury.”); *Fandrey v. Am. Family Mut. Ins.*, 680 N.W.2d 345, 353
25 (Wis. 2004) (“When Wisconsin courts currently speak of ‘cause,’ they do so in the
26 context of the substantial factor test for cause-in-fact.”); *see also* Wis JI-Civil 1500
27 (general causation standard).

1 Defendants contend that the failure to warn claims fail because Plaintiffs cannot
2 show that an adequate warning would have changed Dr. Riebe's decision to use a
3 Recovery filter for Ms. Tinlin. Doc. 15071 at 3, 7-9. The Court does not agree.³

4 Defendants note that Dr. Riebe does not recall seeing the Recovery's instructions
5 for use ("IFU") and does not routinely read IFUs or "dear doctor" letters. Doc. 15071
6 at 8-9. But "it does not follow that he would have ignored any warnings provided by
7 [D]efendants." *Stevens v. Stryker Corp.*, No. 12-CV-63-BBC, 2013 WL 12109101, at *6
8 (W.D. Wis. May 9, 2013). Defendants do not contend that IFUs and "dear doctor" letters
9 are the only avenues by which Bard can provide warnings to physicians. *See* Doc. 15071
10 at 9. Dr. Riebe testified that sales representatives for IVC filter manufacturers, including
11 Bard, visited the hospital where he performed surgery and called on him as a customer
12 throughout his practice. Doc. 15702 ¶ 10; *see* Doc. 15702-1 at 3, 10. Because Bard sales
13 representatives could have personally provided warnings about the Recovery to
14 Dr. Riebe, the fact that he did not read IFUs or "dear doctor" letters does not establish a
15 lack of causation.

16 Dr. Riebe testified that he needed complete and accurate information from medical
17 device manufacturers to help him conduct a proper risk-benefit analysis. Doc. 15702-1
18 at 5. He stated that he would have wanted to know about the Recovery's alleged higher
19 risks of failure, and that Bard did not understand the root causes, did not have a good
20

21 ³ Defendants assert that they had a duty to warn Dr. Riebe, and not Ms. Tinlin
22 directly, under the learned intermediary doctrine. *Id.* at 7-8. The Wisconsin Supreme
23 Court has not decided whether to adopt the doctrine, and federal courts applying
24 Wisconsin law are split on the issue. *See* Doc. 12007 at 14 n.6 (discussing the conflicting
25 case law). The Court need not decide the issue on the present motion because summary
26 judgment is not warranted on the failure to warn claims even under the learned
27 intermediary doctrine. *See Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 968
28 (E.D. Wis. 2009) (because a triable issue existed as to whether the defendant adequately
warned the prescribing physician about the drug's risks, "the 'learned intermediary'
doctrine would not preclude any 'failure to warn' claim, even if the court determined that
the doctrine applied"). Defendants argue in their reply that Plaintiffs cannot prove
causation if the duty to warn is owed to Ms. Tinlin (Doc. 16011 at 3-4), but the Court will
not grant summary judgment based on an argument raised for the first time in a reply
brief. *See Zamani v. Carnes*, 491 F.3d 990, 997 (9th Cir. 2007).

1 understanding of the long-term performance of its retrievable filters or the dynamics of
2 the IVC, had placed the Recovery on hold due to migration problems, and internally
3 found the Recovery to have unacceptable risks. *Id.* at 6-8, 14. This information would
4 have been important for understanding the Recovery's safety and conducting a proper
5 risk-benefit analysis. *Id.* at 8-9, 19; *see* Doc. 15701 ¶¶ 17-22. Bard's knowledge that
6 overweight patients tend to have large expansions of their IVCs, if shared with Dr. Riebe,
7 would have helped him select a filter that would have remained in place in Ms. Tinlin.
8 Doc. 15702-1 at 22; *see* Doc. 15702 ¶ 5.

9 A jury reasonably could infer from this evidence that Bard's failure to warn
10 Dr. Riebe about the Recovery's higher risks of failure, Bard's lack of knowledge about
11 the root causes, and the Recovery's known migration problems in overweight patients
12 was a substantial factor in Dr. Riebe's decision to choose a Recovery for Ms. Tinlin. *See*
13 *Burton v. Am. Cyanamid*, 334 F. Supp. 3d 949, 967 (E.D. Wis. 2018) (denying summary
14 judgment where the jury could draw "the permissible inference . . . that the persons
15 responsible for selecting [the product] would have heeded warnings regarding the risk . . .
16 if such warnings had been issued"); *Stevens*, 2013 WL 12109101, at *6 (finding a triable
17 issue with respect to causation even though the physician generally did not rely on
18 information he received from the defendants when he decided to use their medical
19 device); *Forst*, 602 F. Supp. 2d at 969 (a jury could rely on the prescribing physician's
20 testimony that the lack of warning about the drug's increased risk for suicide prevented
21 him from doing a proper risk-benefit analysis in concluding that his decision to prescribe
22 would have changed); *Michaels v. Mr. Heater, Inc.*, 411 F. Supp. 992, 1007 (W.D. Wis.
23 2006) (denying summary judgment where the jury reasonably could find that the failure
24 to provide adequate warnings was a substantial factor in causing the plaintiff's injuries).⁴

25
26 ⁴ Defendants object to Dr. Riebe's testimony that he would have wanted to know
27 certain information about the Recovery, claiming that the testimony lacks foundation and
28 the questions are incomplete hypotheticals. Doc. 16011 at 5 n.5. But Defendants do not
provide a basis for the objections. Dr. Riebe clearly is qualified to testify about
information he would want to know from IVC filter manufacturers in order to conduct a
proper risk-benefit analysis. Defendants have not shown that this testimony should be
disregarded at the summary judgment stage. *See Quanta Indemnity Co. v. Amberwood*

1 Defendants contend that because Dr. Riebe had no involvement in selecting the
2 IVC filters used at his hospital, and never suggested that any filter other than a Recovery
3 could have been used for Ms. Tinlin, no reasonable inference can be drawn that he would
4 have selected a different filter regardless of what warning Bard provided. Doc. 15071
5 at 9. But Dr. Riebe testified that he often would switch to a Cook Bird's Nest filter for
6 patients with large IVCs. Doc. 15702-1 at 25; *see* Doc. 15702 ¶ 5.

7 Defendants have not shown, as a matter of undisputed fact, that their alleged
8 failure to warn was not a cause of Plaintiffs' injuries. The Court will deny summary
9 judgment on the failure to warn claims.⁵

10 **IV. Misrepresentation Claims (Counts VIII and XII).**

11 Wisconsin common law recognizes three distinct claims of misrepresentation:
12 negligent, strict liability, and intentional or fraudulent. *See Van Den Heuvel v. AI Credit*
13 *Corp.*, 951 F. Supp. 2d 1064, 1073 (E.D. Wis. 2013) (citing *Ollerman v. O'Rourke Co.,*
14 *Inc.*, 288 N.W.2d 95, 99 (Wis. 1980)); *see also Kaloti Enters, Inc. v. Kellogg Sales Co.,*
15 699 N.W.2d 205, 211 (Wis. 2005) (noting that "intentional misrepresentation [is]
16 sometimes referred to as fraudulent misrepresentation"). Each claim requires the plaintiff
17 to show that she relied to her detriment on a false representation of fact. *See Van Den*
18 *Heuvel*, 951 F. Supp. 2d at 1073; *Blenker Bldg. Sys., Inc. v. Array Fin. Servs.*, 340 F.
19 Supp. 3d 792, 797-98 (W.D. Wis. 2018); *Novell v. Migliaccio*, 749 N.W.2d 544, 553

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22

 Dev. Inc., No. CV 11-1807-PHX-JAT, 2014 WL 1246144, at *2 (D. Ariz. March 26,
23 2014) (material that could be presented in a form admissible at trial may be used to avoid
summary judgment).

24 ⁵ Defendants assert that any failure to warn was not the "proximate cause" of
25 Plaintiffs' injuries. Docs. 15071 at 7, 16011 at 5. But the use of "proximate cause" to
26 describe the extent of liability based on lack of causal connection "has long since been
27 abandoned in Wisconsin in favor of the 'substantial factor' test used to establish cause-in-
28 fact, which is a jury issue." *Fandrey*, 680 N.W.2d at 353 (citations omitted); *see*
Michaels, 411 F. Supp. at 1006 (noting that "proximate cause" is "a legal theory that
Wisconsin no longer uses to discuss the causal connection between wrongdoing and
injury"). Under current Wisconsin law, "proximate cause" is "simply short hand for the
public policies a court may consider to deny recovery even if the plaintiff proves
cause-in-fact." *Stevens*, 2013 WL 12109101, at *6. Defendants identify no such public
policies.

1 (Wis. 2008); *Tietsworth v. Harley-Davidson, Inc.*, 677 N.W.2d 233, 239 (Wis. 2004);
2 *Whipp v. Iverson*, 168 N.W.2d 201, 203-204 (Wis. 1969); *see also* Wis JI-Civil 2400.

3 Plaintiffs assert negligent and fraudulent misrepresentation claims. *See* Doc. 364
4 ¶¶ 218-28, 245-59; Doc. 1 at 3, Case No. CV-16-00263. Defendants argue that the
5 claims fail because Plaintiffs cannot show that Ms. Tinlin or Dr. Riebe relied on any Bard
6 representation in selecting a Recovery filter. Doc. 15071 at 9-10. The Court agrees.

7 Plaintiffs assert that a Bard sales representative may have met with Dr. Riebe in
8 the past. Doc. 15696 at 7 (citing Doc. 15702 ¶ 10). But even if this were true, Plaintiffs
9 present no evidence that the sales representative made representations on which
10 Dr. Riebe relied in selecting a Recovery for Ms. Tinlin. Absent such evidence, Plaintiffs
11 cannot establish their misrepresentation claims. *See Blenker Bldg. Sys.*, 340 F. Supp. 3d
12 at 798 (noting that “reliance is an element of all common law misrepresentation claims”)
13 (citing *Novell*, 749 N.W.2d at 553); *Kimberly Area Sch. Dist. v. Zdanovec*, 586 N.W.2d
14 41, 51 (Wis. Ct. App. 1998) (the element of reliance is “common to all types of
15 misrepresentation”).

16 Plaintiffs assert that Dr. Riebe relied on risk-benefit information from those who
17 trained him. Doc. 15696 at 7. Dr. Riebe was trained by Dr. John McDermott, an
18 interventional radiologist at the University of Wisconsin. *Id.* Plaintiffs claim that
19 Dr. McDermott was involved in a 2004 email with Bard employees that downplayed
20 concerns about the number of Recovery migrations in bariatric patients. *Id.*; *see*
21 Doc. 15702-1 at 23. From this evidence, Plaintiffs contend, “[i]t is more than reasonable
22 to infer that Bard’s actions caused Dr. Riebe’s use of the Recovery filter and Ms. Tinlin’s
23 injuries.” Doc. 15696 at 7.

24 But Plaintiffs present no evidence that misleading statements about Recovery
25 migration problems were shared with Dr. Riebe, or that he relied on any such statements
26 in selecting a Recovery for Ms. Tinlin. Moreover, it appears that the “John McDermott”
27
28

1 involved in the email is the former president of Bard Peripheral Vascular, and not the
2 physician who trained Dr. Riebe at the University of Wisconsin. *See* Doc. 16011 at 6-7.⁶

3 Reliance is an essential element of Plaintiff's common law misrepresentation
4 claims. *See Blenker Bldg. Sys.*, 340 F. Supp. 3d at 798; *Kimberly Area Sch. Dist.*, 586
5 N.W.2d at 51. Plaintiffs have failed to make a showing sufficient to establish the
6 existence of this element. The Court will grant summary judgment on the negligent and
7 fraudulent misrepresentation claims. *See Celotex*, 477 U.S. at 322; *Valente v. Sofamor*,
8 *S.N.C.*, 48 F. Supp. 2d 862, 877 (E.D. Wis. 1999) (granting summary judgment where
9 "the plaintiffs [did] not present evidence to show that they or their doctors relied on the
10 defendants' alleged misrepresentations regarding the efficacy and safety of [their] pedicle
11 screw device"); *Staudt v. Artifex Ltd.*, 16 F. Supp. 2d 1023, 1031 (E.D. Wis. 1998)
12 (granting summary judgment where the plaintiff failed to point to any evidence that he
13 relied on the defendants' misrepresentations about their spinal devices); *Collins v. Eli*
14 *Lilly Co.*, 342 N.W.2d 37, 54 (Wis. 1984) (granting summary judgment on a
15 misrepresentation claim because "[e]ven assuming that the defendants made
16 misrepresentations concerning [their drug], since there was no reliance on those
17 misrepresentations, there can be no recovery under this cause of action").

18 **V. Concealment Claim (Count XIII).**

19 A defendant is liable for fraudulent concealment in Wisconsin "when, having a
20 duty to disclose, he intentionally fails to do so with the intent to deceive the plaintiff and
21 thereby induces the plaintiff to act to his or her detriment." *Schmidt v. Bassett Furniture*
22 *Indus.*, No. 08-C-1035, 2009 WL 3380354, at *10 (E.D. Wis. Oct. 20, 2009) (citing
23 *Kaloti Enters.*, 699 N.W.2d at 211-12); *see Ollerman*, 288 N.W.2d at 100 (noting that the
24 "failure to disclose [a] fact is treated in the law as equivalent to a representation of the
25

26 ⁶ In the email, McDermott wrote to various high-level Bard employees that
27 "we have had several discussions with physicians about bariatric patients and I've asked
28 our Filter team to summarize what we know to date." Doc. 15702-2 at 2 (emphasis
added). He further stated that he would provide a "summary of our filter complaints
[and] shipments." *Id.* A copy of the email provided by Defendants shows McDermott's
email address as "John.McDermott@crbard.com." Doc. 16011-1 at 2.

1 non-existence of the fact.”). Plaintiffs allege that Defendants failed to disclose, among
2 other things, that Bard filters had higher risks of complications than other IVC filters.
3 *See* Doc. 364 ¶¶ 261-62.

4 Defendants contend that there is no evidence showing that Bard’s alleged
5 concealment of adverse information about the Recovery caused Plaintiffs’ injuries.
6 Doc. 15071 at 10. But as explained above, Dr. Riebe testified that he expected Bard to
7 warn him about the Recovery’s higher risks of complications. *See* Docs. 15701 ¶¶ 17-22,
8 15702-1 at 5-9, 12-19. He explained that a manufacturer’s concealment of true risks
9 prevents him from conducting a proper risk-benefit analysis. Doc. 15702-1 at 5. A jury
10 reasonably could conclude from this evidence that Bard’s failure to disclose the
11 Recovery’s true risks was a cause of Dr. Riebe’s decision to use the device for
12 Ms. Tinlin, and her resulting injuries. The Court will deny summary judgment on the
13 concealment claim.

14 **VI. Deceptive Trade Practices Act Claim (Count XIV).**

15 Plaintiffs assert a violation of Wisconsin’s Deceptive Trade Practices Act,
16 Wis. Stat. § 100.18. *See* Doc. 364 ¶ 321; Doc. 1 at 4, Case No. CV-16-00263. The
17 statute prohibits sellers from making, with the intent to induce the public to enter into an
18 obligation relating to the purchase of goods, any representation that is untrue, deceptive,
19 or misleading. § 100.18(1). The statute provides a private right of action for “[a]ny
20 person suffering pecuniary loss because of a violation[.]” § 100.18(11)(b)(2). “[T]here
21 are three elements in a § 100.18 cause of action: (1) the defendant made a representation
22 to the public with the intent to induce an obligation, (2) the representation was ‘untrue,
23 deceptive or misleading,’ and (3) the representation materially induced (caused) a
24 pecuniary loss to the plaintiff.” *Novell*, 749 N.W.2d at 553 (citing *K & S Tool & Die*
25 *Corp. v. Perfection Mach. Sales, Inc.*, 732 N.W.2d 792, 798 (Wis. 2007)); *see Skyrise*
26 *Constr. Grp. v. Annex Constr., LLC*, No. 18-CV-381, 2019 WL 699964, at *6 (E.D. Wis.
27 Feb. 20, 2019); Wis JI-Civil 2418.

1 Defendants argue that Plaintiffs' § 100.18 claim fails for lack of causation.
2 Doc. 15071 at 10. Plaintiffs do not dispute that causation is an essential element of such
3 a claim. *See* Doc. 15696 at 8 (citing *Andersen v. Vavreck*, No. 15-CV-667-PP, 2017 WL
4 680424, at *3 (E.D. Wis. Feb. 21, 2017) (a plaintiff asserting a violation of § 100.18 must
5 show that "the representation caused him to suffer a pecuniary loss")). Rather, Plaintiffs
6 cite *Novell* for the proposition that a § 100.18 claim requires no element of reliance. *Id.*

7 But the question in *Novell* was "whether *reasonable* reliance is a necessary
8 element in a § 100.18 claim." 749 N.W.2d at 551 (emphasis in original). The *Novell*
9 court made clear that although reasonable reliance is not an element, "[r]eliance is an
10 aspect of the third element, whether a representation *caused* the plaintiff's pecuniary
11 loss." 749 N.W.2d at 553 (emphasis added); *see Ramsden v. Farm Credit Servs.*
12 *of N. Cent. Wis. ACA*, 590 N.W.2d 1 (Wis. Ct. App. 1998) (noting that reliance in a
13 misrepresentation claim is equivalent to the causation element in a traditional negligence
14 claim). Wisconsin district courts have read *Novell* "to mean that satisfying the element of
15 causation for a claim under § 100.18 requires more than a showing by the plaintiff that it
16 sustained a loss that is somehow connected to a misrepresentation made to 'the public.'" *Grice Eng'g, Inc. v. JG Innovations, Inc.*, 691 F. Supp. 2d 915, 923 (W.D. Wis. 2010)
17 (citing *Spacesaver Corp. v. Marvel Grp., Inc.*, 621 F. Supp. 2d 659, 663 (W.D. Wis.
18 2009)). Rather, "the question is whether 'the representation materially induced the
19 plaintiff's decision to act and whether the plaintiff would have acted in the absence of the
20 representation.'" *Id.* (quoting *Novell*, 749 N.W.2d at 554; alterations omitted); *see also*
21 *Tim Torres Enters. v. Linscott*, 416 N.W.2d 670, 675 (Wis. Ct. App. 1987) (interpreting
22 § 100.18 "as requiring some proof beyond the content of the advertisement itself to
23 establish that the plaintiff was in fact damaged by it"); Wis JI-Civil 2418 (in determining
24 whether the plaintiff's loss was caused by the defendant's representation, "the test is
25 whether [the plaintiff] would have acted in its absence").

26
27 Plaintiffs assert that the record is replete with examples of Bard's misleading
28 statements to the public. Doc. 15696 at 9. But Plaintiffs present no evidence showing

1 that the statements materially induced Ms. Tinlin or Dr. Riebe to select a Recovery filter,
2 or that a different filter would have been selected in the absence of the statements.
3 Without such evidence, Plaintiffs cannot show that the statements caused them to suffer a
4 pecuniary loss. The Court will grant summary judgment on the § 100.18 claim. *See*
5 *Valente*, 48 F. Supp. 2d at 874 (granting summary judgment where “the plaintiffs [did]
6 not show that they or their doctors relied on the defendants’ allegedly fraudulent
7 representations when they elected to undergo spinal fusion surgery [and therefore could]
8 not show a causal connection between the defendants’ alleged conduct and any pecuniary
9 loss suffered as a result of their continued back pain”); *Monson v. Acromed Corp.*, No.
10 96-C-1336, 1999 WL 1133273, at *24 (E.D. Wis. May 12, 1999) (finding summary
11 judgment warranted regardless of whether reliance is an element of a § 100.18 claim
12 because the record was devoid of evidence showing a causal connection between the
13 defendants’ statements and the plaintiff’s loss); *Andersen*, 2017 WL 680424, at *3
14 (granting summary judgment where the plaintiff “failed to make a sufficient showing that
15 his damages were caused by the defendants’ conduct”).

16 **VII. Design Defect Claims (Counts III and IV).**

17 Plaintiffs assert strict liability and negligent design defect claims. *See* Doc. 364
18 ¶¶ 182-97; Doc. 1 at 3, Case No. CV-16-00263. Defendants contend that each claim fails
19 because Plaintiffs offer no reasonable alternative design for the Recovery. Doc. 15071
20 at 10-13. The Court does not agree.⁷

21 Defendants do not dispute that Plaintiffs’ engineering expert, Dr. Robert
22 McMeeking, offers several alternative designs to the Recovery that he believes would

23
24 ⁷ Wisconsin’s strict liability statute, Wis. Stat. § 895.047, expressly requires
25 evidence of a reasonable alternative design to show that a product is defective.
26 § 895.047(1)(a); *see also Janusz v. Symmetry Med. Inc.*, 256 F. Supp. 3d 995, 1000 (E.D.
27 Wis. 2017); Wis. JI-Civil 3260.1. Defendants contend that such evidence is also required
28 to establish a negligent design claim. Doc. 15071 at 10-11 (citing *Below v. Yokohama*
Tire Corp., No. 15-CV-529-WMC, 2017 WL 679153, at *3 (W.D. Wis. Feb. 21, 2017)
(noting that “the two theories are similar . . . because the reasonableness of a product’s
design turns essentially on whether the seller could have come up with a less dangerous
design”). The Court need not decide the issue for purposes of summary judgment
because Plaintiffs have presented sufficient evidence of a reasonable alternative design.

1 have helped reduce the risk of the failures that occurred in Ms. Tinlin’s filter.
2 Doc. 15071 at 11. Specifically, Dr. McMeeking opines that “reasonable alternative
3 designs and alternative features available to Bard before Ms. Tinlin received her filter
4 include . . . caudal anchors, penetration limiters, two-tier design, and a better (smoother
5 and rounded) chamfer at the mouth of the ‘cap’ on the filter.” Doc. 15073 ¶ 21; *see*
6 Doc. 15074-3 at 3. Dr. McMeeking explains that “[m]any of these design features
7 existed in other IVC filter products already on the market, including the Simon Nitinol
8 Filter, the Cook Gunther Tulip filter, the Greenfield filter, and the Cook Bird’s Nest
9 filter.” Doc. 15701 ¶ 30; *see* Doc. 15071-8 at 4. A jury reasonably could find from this
10 evidence that specific and reasonable alternative design changes were available when
11 Defendants developed the Recovery. *See Rogers v. K2 Sports, LLC*, 348 F. Supp. 3d 892,
12 902-03 (W.D. Wis. 2018) (denying summary judgment where the plaintiff’s expert
13 opined that the helmet in question did not provide sufficient protection due to a tapered
14 edge while other helmets without tapering provided the necessary protection); *see also*
15 Docs. 12007 at 13, 12805 at 5-6 (finding in the Hyde case that Dr. McMeeking’s
16 opinions constituted sufficient evidence that reasonable alternative designs were available
17 to Bard when it developed the G2X and Eclipse filters).⁸

18 Defendants contend that permanent IVC filters, such as the Simon Nitinol filter
19 (“SNF”), are not reasonable alternative designs for the retrievable Recovery. Doc. 15071
20 at 11-13. But the Recovery was designed and cleared for permanent use (Doc. 7950
21 ¶¶ 8, 17), and Plaintiffs have presented evidence that Ms. Tinlin’s filter remains
22 implanted as a permanent device (Doc. 15701 ¶¶ 23-24). Whether the retrievability of
23 the Recovery makes it sufficiently unlike the SNF and other permanent filters to
24 disqualify them as reasonable alternative designs is a question for the jury to decide. *See*
25 Doc. 12805 at 6.⁹

26
27 ⁸ Defendants note that summary judgment would be warranted if their motions to
28 exclude Dr. McMeeking’s opinions are granted (Doc. 15071 at 11), but the motions were
denied in relevant respects (Doc. 16992).

⁹ Defendants’ reliance on *Oden v. Boston Scientific Corp.*, 2018 U.S. Dist. LEXIS

1 Defendants further contend that the Cook filters and Bard's later-generation filters
2 are not reasonable alternative designs because Dr. McMeeking believes they are
3 defective. Doc. 15071 at 13. Defendants cite *Tunnel v. Ford Motor Co.*, 385 F. Supp. 2d
4 582 (W.D. Va. 2005), which found that Virginia requires a showing that "the proposed
5 alternative would truly cure a product of its alleged defects[.]" 385 F. Supp. 2d at 586.
6 But a manufacturer may be liable under Wisconsin's product liability statute where the
7 alternative design would have "reduced" the harm posed by the product. Wis. Stat.
8 § 895.047(1)(a); see Doc. 12007 at 13. Defendants do not dispute that specific
9 alternative design features identified by Dr. McMeeking – caudal anchors, penetration
10 limiters, and a chamfered cap – help reduce the risk of filter failures like those
11 experienced by Ms. Tinlin.¹⁰

12 Plaintiffs have presented sufficient evidence of a reasonable alternative design.
13 The Court will deny summary judgment on the design defect claims. See *Rogers*, 348 F.
14 Supp. 3d at 902-03.¹¹

15 **VIII. Future Damages.**

16 Wisconsin law holds that future injuries and healthcare must be established by a
17 medical probability. See *Pucci v. Rausch*, 187 N.W.2d 138, 142 (Wis. 1971) (citing
18 cases). "But medical probability does not mean absolute certainty or metaphysical
19 certainty." *Reyes v. Greatway Ins.*, 582 N.W.2d 480, 485 (Wis. Ct. App. 1998). As long

20
21 102639 (E.D.N.Y. June 4, 2018), is misplaced because the case involved the granting of a
22 motion to dismiss where the plaintiff had received a permanent filter and alleged that
23 retrievable filters were not designed to be permanent. *Id.* at *12-13. Although Dr. Riebe
found Ms. Tinlin to be a candidate for a retrievable filter (Doc. 15073 ¶ 5), the Recovery
also can serve as a permanent device (see Docs. 7950 ¶¶ 8, 15701 ¶ 24).

24 ¹⁰ Defendants note in their reply that Dr. McMeeking agrees that his proposed
25 design changes may not have "avoided" Ms. Tinlin's injuries. Doc. 16011 at 8. But as
explained above, it is sufficient that the alternative design would have "reduced" the risk
of harm. Wis. Stat. § 895.047(1)(a).

26 ¹¹ Given this ruling and the denial of summary judgment on the claims for failure
27 to warn and concealment, Mr. Tinlin's claim for loss of consortium (Count XV) survives
28 summary judgment. See Doc. 15071 at 3, 14; *Finnegan v. Wis. Patients Comp. Fund*,
666 N.W.2d 797, 805 (Wis. 2003) ("[A] derivative claim for loss of consortium or loss of
society and companionship does not have its own elements distinct from the negligence
claim to which it attaches[.]") (citing Wis JI-Civil 1815).

1 as an expert's opinion is based on probability, and not mere possibility or conjecture, the
2 opinion is sufficient to support an award of future damages. *Weber v. White*, 681 N.W.2d
3 137, 143 (Wis. 2004). Defendants contend that Plaintiffs' medical experts could not
4 opine that Ms. Tinlin "probably" will have future complications and medical expenses
5 from her Recovery filter. Doc. 15071 at 14-15.

6 **A. Dr. Derek Muehrcke.**

7 Dr. Muehrcke testified that he believes Ms. Tinlin is at future risk for various
8 complications from her Recovery filter because the filter disintegrated, sending multiple
9 fragments to the heart and lungs, and the filter remains unstable with several missing
10 arms. Doc. 15702-4 at 7-8. He opines that Ms. Tinlin's risk of future complications is
11 40 percent at five and half years. Doc. 15704-5 at 8. He holds these opinions to a
12 reasonable degree of medical probability. Doc. 15702-4 at 8.

13 Dr. Muehrcke's opinions are expressed "not in terms of 'possibilities' but
14 'probabilities[.]'" *Bleyer*, 120 N.W.2d at 160. The opinions therefore are sufficient to
15 support a jury finding that Ms. Tinlin probably will suffer future injuries from the
16 Recovery which will require further medical treatment. *See id.*; *Weber*, 681 N.W.2d
17 at 143 (noting that Wisconsin law "does not require mathematical certainty" to establish
18 future medical care and finding the expert's estimate that the plaintiff's future care would
19 "probably be around 20 to 25 visits a year . . . on an average" sufficient to support an
20 award of future chiropractic expenses); *Reyes*, 582 N.W.2d at 485 (finding that the
21 "doctor's use of the term 'significant chance' indicates an opinion to a reasonable degree
22 of medical probability"); *Pucci*, 187 N.W.2d at 142 (noting that opinions expressed in
23 terms of "I feel" or "I believe" have been held to be sufficient) (citing *Hintz v. Mielke*,
24 112 N.W.2d 720, 725 (Wis. 1961)). The Court will deny summary judgment with respect
25 to the future injuries and medical care opined to by Dr. Muehrcke.¹²

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27
28 ¹² Defendants note that Dr. Muehrcke did not perform a differential diagnosis for
Ms. Tinlin's shortness of breath, but make no argument as to why this warrants summary
judgment. Doc. 15071 at 14.

1 **B. Dr. Darren Hurst.**

2 Defendants assert that Dr. Hurst could not opine that Ms. Tinlin probably will
3 experience pneumothorax, abscess, and lung hemorrhage in the future. Doc. 15071 at 15
4 (citing Doc. 15073 ¶¶ 34-35). Defendants contend that the monitoring and medical
5 intervention costs that Dr. Hurst recommends for these conditions should not be
6 compensable, but specifically identify only the costs for lung resection and life-long CT
7 scans. *Id.*

8 **1. Lung Resection.**

9 Dr. Hurst states in his report that three filter arms embolized in Ms. Tinlin’s right
10 lung, but makes clear that “the future behavior and possible morbidity and mortality of
11 these embolized arms *is currently unknown.*” Doc. 15074-6 at 3 (emphasis added). He
12 further states that filter fragments in the lungs of other patients have resulted in
13 pneumothorax, abscess, and lung hemorrhage, and the filter arms in Ms. Tinlin’s lung
14 will require lung resection for removal “if they become symptomatic[.]” *Id.* But
15 Dr. Hurst does not know whether it is probable that the filter arms will cause
16 pneumothorax, abscess, or lung hemorrhage. He testified that “[f]or all of these potential
17 complications, there’s no data,” there “are only case reports of similar types of objects in
18 the lungs that have caused these problems,” and “[n]o one has done a long-term study
19 because it is so new.” Doc. 15074-7 at 7.

20 This testimony shows that the risk of future complications from the filter arms in
21 Ms. Tinlin’s lung is a mere possibility, and “an expert opinion expressed in terms of a
22 ‘mere possibility’ is insufficient to sustain a finding” of future damages. *Bleyer v. Gross*,
23 120 N.W.2d 156, 160 (Wis. 1963); *see McGarrity v. Welch Plumbing Co.*, 312 N.W.2d
24 37, 44-45 (Wis. 1981) (“The court of appeals correctly held that an expert opinion
25 expressed in terms of possibility or conjecture is insufficient[.]”). The Court will grant
26 summary judgment on future medical costs for a lung resection.

27 ///

28 ///

1 **b. CT Scans.**

2 The Court reaches a difference conclusion with respect to future CT scans.
3 Dr. Hurst opines that the filter arms in Ms. Tinlin’s lung “*will require* life-long follow up
4 with CT imaging to document their stability.” Doc. 15074-6 at 3 (emphasis added). He
5 testified that he “think[s] she probably will need a CT [scan] either every year or every
6 other year to just make sure that she’s not developing an issue related to the fragments.”
7 Doc. 15701-7 at 3. This evidence is sufficient to support an award for the costs of future
8 CT scans. *See Weber*, 681 N.W.2d at 143; *Pucci*, 187 N.W.2d at 142. The Court will
9 deny summary judgment in this regard.

10 **3. Chronic Cough and Asthma.**

11 Defendants contend that Dr. Hurst could not determine whether Ms. Tinlin’s
12 chronic cough and exacerbation of her asthma are related to her filter. Doc. 15071 at 15
13 (citing Doc. 15073 ¶ 37). But Dr. Hurst found that the chronic cough “is almost certainly
14 related to her tracheomalacia.” Doc. 15704-7 at 3.¹³ He further found that the
15 tracheomalacia “would exacerbate asthma.” *Id.* at 4. This evidence is sufficient to
16 support a finding that Ms. Tinlin’s chronic cough and asthma problems are related to her
17 Recovery filter. The Court will deny summary judgment on this issue.¹⁴

18 **IT IS ORDERED:**

19 1. The following claims are **dismissed** based on Plaintiffs’ withdrawal of the
20 claims before Defendants moved for summary judgment: manufacturing defect (Counts I
21 and V), failure to recall (Count VI), negligence per se (Count IX), and breach of warranty
22 (Counts X and XI).

23 _____

24 ¹³ Ms. Tinlin’s tracheomalacia presumably was caused by the tracheotomy
25 procedure during her open heart surgery to remove a fractured strut from the right
ventricle.

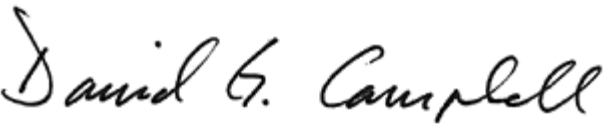
26 ¹⁴ Defendants assert in their reply that future medical costs are compensable only
27 if they are “reasonably certain” to occur. Doc. 16011 at 10 (citing *Meracle v. Children’s*
28 *Serv. Soc’y of Wis.*, 437 N.W.2d 532, 535 (Wis. 1989)). But Defendants have not shown
that this standard differs from the “probability” standard applied above. *See Meracle*,
437 N.W.2d at 535 (noting that *Bleyer* similarly held that medical testimony about future
expenses must be expressed “not in terms of ‘possibilities’ but ‘probabilities’ ”).

1 2. Defendants' motion for summary judgment (Doc. 15071) is **granted in**
2 **part and denied in part** as follows:

3 a. The motion is **granted** on Plaintiffs' misrepresentation and
4 deceptive trade practices claims (Counts VIII, XII, and XIV), and future costs for a lung
5 resection.

6 b. The motion is **denied** on Plaintiffs' claims for failure to warn
7 (Counts II and VII), design defect (Count III and IV), fraudulent concealment (Count
8 XIII), and loss of consortium (Count XV), and future medical costs for CT scans, chronic
9 cough, and asthma.

10 Dated this 16th day of April, 2019.

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14 David G. Campbell
15 Senior United States District Judge
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1 **WO**

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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**
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9 IN RE: Bard IVC Filters Products
10 Liability Litigation,
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No. MDL 15-02641-PHX-DGC
ORDER

13
14 The Plaintiffs Steering Committee (“PSC”) moves to modify Case Management
15 Order No. 6 (“CMO 6”) to increase the common benefit assessments. Doc. 16932 at 3-6.
16 Defendants and counsel for many individual plaintiffs oppose the proposed increases.
17 Docs. 17367, 17387-17404, 17433, 17555. A hearing was held on May 29, 2019.
18 Doc. 17966. For reasons stated below, the Court will grant the motion in part and deny it
19 in part.

20 **I. CMO 6 – Common Benefit Funds and Assessments.**

21 CMO 6 was issued early in this MDL to provide for the fair and equitable sharing
22 among plaintiffs and their counsel of the burden of litigating this complex case. Doc. 372
23 at 1. CMO 6 provides that compensable common benefit work includes meetings and
24 conference calls, court appearances, discovery, document review, expert retention and
25 development, legal research, motion practice, bellwether cases and trials, settlement
26 efforts, and all other work that advances this litigation to conclusion. *Id.* at 1-2, 7-8. The
27 time spent performing common benefit work must be authorized by Plaintiffs’ Co-Lead
28 Counsel and recorded accurately and contemporaneously. *Id.* at 8-9.

1 CMO 6 provides for the establishment of two interest-bearing accounts to receive
2 and disburse common benefit funds: the “Bard IVC Filters Fee Fund” and the “Bard IVC
3 Filters Expense Fund.” *Id.* at 9. The Court has granted the PSC’s request to establish these
4 accounts and has appointed Citibank, N.A., as escrow agent. *See* Docs. 17777, 16932
5 at 2-3. The accounts will be funded through assessments on the gross monetary recoveries
6 received by plaintiffs and their counsel in this MDL. *Id.* at 9. The current total assessment
7 amount is 8%, which includes 6% for attorneys’ fees and 2% for expenses. *Id.* at 10.

8 **II. The PSC’s Motion to Increase the Assessment Percentages.**

9 The PSC proposes to increase the attorneys’ fees assessment to 9% and the expense
10 assessment to 5%. Doc. 16932 at 3. The PSC contends that the duration, scope, size, and
11 cost of this litigation have outstripped the PSC’s expectations when it proposed the initial
12 assessment percentages. *Id.* The PSC further contends that the current percentages are
13 conservative and MDL courts routinely approve increases as litigation develops. *Id.* at 4-5.

14 **A. The Litigation’s Duration and Scope.**

15 Given that Bard had been litigating IVC filter cases for years when the MDL was
16 formed in late 2015, the PSC asserts that “trials stretching into 2019 seemed unlikely.” *Id.*
17 at 4. The Court cannot conclude that bellwether trials were unforeseeable when CMO 6
18 was entered. Such trials are commonplace in mass tort MDLs and were discussed at the
19 first case management conference. *See* Doc. 174 at 25-26.

20 The PSC estimated, however, that all bellwether trials would conclude by April
21 2017. *Id.* at 25. The final bellwether trial ultimately was scheduled for May 2019 – more
22 than two years later than the PSC expected. Moreover, the parties did not complete all
23 common discovery and file dispositive motions until late 2017, nearly a year longer than
24 the PSC expected. *Id.* at 24-25. Although the overall duration of this litigation is not long
25 for a mass tort MDL, the PSC’s initial expectation that the litigation would end sooner was
26 not unreasonable.

27 The common benefit work has included millions of pages of document review,
28 substantial ESI discovery, dozens of depositions, many experts and Daubert challenges,

1 multiple summary judgment motions, numerous motions in limine, three three-week
2 bellwether trials, post-trial motions and appeals, and substantial settlement efforts.
3 Defendants' preemption motion involved more discovery and was more complex than the
4 PSC anticipated. Several trial preservation depositions will yet be taken, and the PSC has
5 agreed to prepare trial packets for lawyers whose cases are remanded or transferred.

6 The PSC states that while it was prepared for protracted litigation, it did not fully
7 anticipate the scope of this MDL when it proposed the initial assessment percentages.
8 Doc. 17687 at 3. The Court finds there was significant unanticipated common benefit work
9 that justifies an increase in the attorneys' fees assessment percentage. The Court will
10 increase the attorneys' fees assessment from 6% to 8%. The Court will not grant the
11 requested increase to 9% because the Court does not agree with the PSC's argument that
12 this case will include a significant amount of future work by the PSC. During oral
13 argument, Mr. Lopez noted that some transferor courts may allow the parties to take
14 updated depositions of Bard or other witnesses and that members of the PSC may be asked
15 to consult with lawyers who try cases in transferor courts. Even if true, the Court does not
16 view these as responsibilities of the PSC that should be charged to the common benefit.

17 The Court notes that the 8% assessment for attorneys' fees represents a holdback,
18 not a determination of the final amount to be disbursed out of the common benefit fee fund.
19 *See* Doc. 372 at 10.

20 **B. Reliance on the Current Assessment Percentages.**

21 In February 2019, the parties informed the Court that a large number of cases had
22 settled in principle and many others were near settlement. *See* Doc. 15176, 15629. Nearly
23 2,000 of the cases settled in principle by execution of a settlement term sheet have been
24 brought by the law firms of Freese & Goss and Matthews & Associates. Doc. 17367 at 1.
25 Counsel from these settling law firms and Defendants have represented that another 2,000
26 or so cases are near settlement. The settling law firms argue that they relied on the 6%
27 attorneys' fees assessment in negotiating the settlements, and that it would be unfair to
28 increase the assessment at this late date. Docs. 17367 at 2-3, 17404 at 2. Other law firms

1 with cases in this MDL have joined these arguments. Docs. 17367, 17387-17403, 17433,
2 17555.

3 The purpose of a common benefit fund is to ensure that attorneys who perform work
4 that benefits all plaintiffs and their counsel are reasonably compensated. The PSC
5 managed and litigated this complex litigation to a conclusion, obtained a \$3.6 million jury
6 verdict in the Booker case and a fair settlement in the Tinlin case, withstood Defendants'
7 preemption challenge to the viability of every plaintiffs' claims, and amassed evidence and
8 experts that benefit all plaintiffs and their counsel. The settling law firms do not challenge
9 the quality of this work, nor do they dispute that the work benefitted them and their clients
10 significantly.

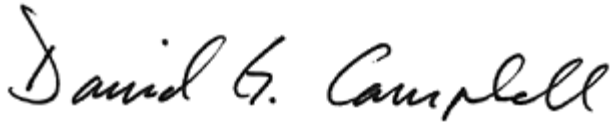
11 The justifiable reliance argument of the settling law firms has persuasive force, but
12 the Court concludes that simple fairness requires that these firms – which will benefit
13 financially from the work of the PSC – pay reasonable compensation to the lawyers who
14 secured the benefit. The Court also notes that the PSC's motion is based in part on
15 uncertainty about settlement values because Defendants and the settling law firms have
16 declined to disclose the terms of their settlement agreements, even to the PSC. In light of
17 this uncertainty, the PSC believes that the current 6% assessment for attorneys' fees may
18 not be sufficient to reasonably compensate the PSC for the tens of thousands of hours of
19 common benefit work performed to date. *Id.* at 3-4. This is a legitimate concern. The
20 Court has no information about the value of the settlements reached to date, and concludes
21 that this is another reason to increase the attorneys' fee assessment to 8%.

22 The Court reaches a difference conclusion with respect to costs. The justifiable
23 reliance argument is more compelling when applied to individual plaintiffs. Although the
24 PSC initially argued that an increased assessment would not change the amounts individual
25 plaintiffs would receive in any settlement (Doc. 17687 at 2), it acknowledged at the hearing
26 that costs generally are born by clients and the proposed 3% increase would be paid directly
27 by individual plaintiffs, including those who have already agreed on settlement terms with
28 Defendants. The Court is more concerned about increasing the amount of costs to be borne

1 by individual plaintiffs (especially after they have reached a settlement in principle) than
2 it is about requiring lawyers to pay their fair share of the work that secured settlements for
3 their cases. The Court will not increase cost amounts for individual plaintiffs at this late
4 date.

5 **IT IS ORDERED:** The PSC's motion to modify CMO 6 (Doc. 16932 at 3-6) is
6 **granted in part and denied in part.** The attorneys' fees assessment is increased from 6%
7 to 8%. The 2% expense assessment is not changed. The first sentence of Section IV(B)(3)
8 of CMO 6 is amended to read as follows: "The assessment amount is 10%, which includes
9 8% for attorneys' fees and 2% for expenses." *See* Doc. 372 at 10.

10 Dated this 31st day of May, 2019.

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14 David G. Campbell
15 Senior United States District Judge
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